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

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended April 2, 2021

or

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

Commission File Number: 000-30235

EXELIXIS, INC.

(Exact name of registrant as specified in its charter)

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

1851 Harbor Bay Parkway
Alameda, CA 94502
(650) 837-7000

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock $.001 Par Value per Share	**EXEL**	**The Nasdaq Stock Market LLC**

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ 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	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Securities Act. ☐

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

As of April 26, 2021, there were 313,387,205 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 per share amounts)
(unaudited)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 370,209	$ 319,217
Short-term investments	815,285	887,319
Trade receivables, net	177,673	160,875
Inventory	24,757	20,973
Prepaid expenses and other current assets	46,341	57,011
Total current assets	1,434,265	1,445,395
Long-term investments	328,860	330,751
Property and equipment, net	78,453	67,384
Deferred tax assets, net	160,598	156,711
Goodwill	63,684	63,684
Other long-term assets	124,682	73,408
Total assets	$ 2,190,542	$ 2,137,333
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,821	$ 23,632
Accrued compensation and benefits	37,945	51,189
Accrued clinical trial liabilities	59,762	52,251
Rebates and fees due to customers	31,468	20,683
Accrued collaboration liabilities	13,461	12,456
Other current liabilities	56,880	44,447
Total current liabilities	213,337	204,658
Long-term portion of deferred revenues	9,760	3,755
Long-term portion of operating lease liabilities	52,837	49,086
Other long-term liabilities	3,421	721
Total liabilities	279,355	258,220
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares issued	—	—
Common stock, $0.001 par value; 400,000 shares authorized; issued and outstanding: 313,262 and 311,627 at March 31, 2021 and December 31, 2020, respectively	313	312
Additional paid-in capital	2,354,103	2,321,895
Accumulated other comprehensive income	2,740	4,476
Accumulated deficit	(445,969)	(447,570)
Total stockholders' equity	1,911,187	1,879,113
Total liabilities and stockholders' equity	$ 2,190,542	$ 2,137,333

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

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

	Three Months Ended March 31,	
	2021	**2020**
Revenues:		
Net product revenues	$ 227,212	$ 193,880
License revenues	27,528	20,879
Collaboration services revenues	15,490	12,156
Total revenues	270,230	226,915
Operating expenses:		
Cost of goods sold	13,198	9,289
Research and development	159,288	101,877
Selling, general and administrative	102,351	62,940
Total operating expenses	274,837	174,106
Income (loss) from operations	(4,607)	52,809
Interest income	2,682	7,220
Other income (expense), net	(90)	6
Income (loss) before income taxes	(2,015)	60,035
Provision for (benefit from) income taxes	(3,616)	11,423
Net income	$ 1,601	$ 48,612
Net income per share:		
Basic	$ 0.01	$ 0.16
Diluted	$ 0.00	$ 0.15
Weighted-average common shares outstanding:		
Basic	312,473	305,388
Diluted	321,287	315,839

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,	
	2021	**2020**
Net income	$ 1,601	$ 48,612
Other comprehensive income (loss):		
Net unrealized losses on available-for-sale debt securities, net of tax impact of $499 and $941, respectively	(1,736)	(3,291)
Comprehensive income (loss)	$ (135)	$ 45,321

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

EXELIXIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)
(unaudited)

	Three Months Ended March 31, 2021					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	311,627	$ 312	$2,321,895	$ 4,476	$ (447,570)	$ 1,879,113
Net income	—	—	—	—	1,601	1,601
Other comprehensive loss	—	—	—	(1,736)	—	(1,736)
Issuance of common stock under equity incentive plans	1,635	1	4,201	—	—	4,202
Stock transactions associated with taxes withheld on equity awards	—	—	(6,646)	—	—	(6,646)
Stock-based compensation	—	—	34,653	—	—	34,653
Balance at March 31, 2021	313,262	$ 313	$2,354,103	$ 2,740	$ (445,969)	$ 1,911,187

	Three Months Ended March 31, 2020					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	304,831	$ 305	$2,241,947	$ 3,069	$ (559,351)	$ 1,685,970
Net income	—	—	—	—	48,612	48,612
Other comprehensive loss	—	—	—	(3,291)	—	(3,291)
Issuance of common stock under equity incentive plans	949	1	4,171	—	—	4,172
Stock transactions associated with taxes withheld on equity awards	—	—	(1,793)	—	—	(1,793)
Stock-based compensation	—	—	13,982	—	—	13,982
Balance at March 31, 2020	305,780	$ 306	$2,258,307	$ (222)	$ (510,739)	$ 1,747,652

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,	
	2021	**2020**
Net income	$ 1,601	$ 48,612
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	3,227	2,175
Stock-based compensation	34,653	13,982
Non-cash lease expense	1,221	1,174
Deferred taxes	(3,388)	10,128
Other, net	6,578	(888)
Changes in operating assets and liabilities:		
Trade receivables, net	(17,690)	(18,270)
Inventory	(2,090)	(4,695)
Prepaid expenses and other assets	1,872	(2,863)
Deferred revenue	13,422	8,850
Accounts payable and other liabilities	138	(2,131)
Net cash provided by operating activities	39,544	56,074
Cash flows from investing activities:		
Purchases of property, equipment and other	(13,557)	(2,961)
Purchases of investments	(331,612)	(251,505)
Proceeds from maturities and sales of investments	407,424	287,086
Net cash provided by investing activities	62,255	32,620
Cash flows from financing activities:		
Proceeds from issuance of common stock under equity incentive plans	2,791	3,938
Taxes paid related to net share settlement of equity awards	(5,441)	(1,793)
Net cash (used in) provided by financing activities	(2,650)	2,145
Net increase in cash, cash equivalents and restricted cash equivalents	99,149	90,839
Cash, cash equivalents and restricted cash equivalents at beginning of period	320,772	268,137
Cash, cash equivalents and restricted cash equivalents at end of period	$ 419,921	$ 358,976
Supplemental cash flow disclosures:		
Non-cash operating activities:		
Right-of-use assets obtained in exchange for lease obligations	$ 4,893	$ 576

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 an oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Our drug discovery and development capabilities and commercialization platform are the foundations upon which we intend to bring to market novel, effective and tolerable therapies to provide cancer patients with additional treatment options.

Since we were founded in 1994, four products resulting from our discovery efforts have progressed through clinical development, received regulatory approval and established a commercial presence in various geographies around the world. Two are derived from cabozantinib, our flagship molecule, an inhibitor of multiple tyrosine kinases including MET, AXL, VEGF receptors and RET. Our cabozantinib products are: CABOMETYX® (cabozantinib) tablets approved for advanced renal cell carcinoma (RCC), both alone and in combination with Bristol Myers Squibb Company's OPDIVO® (nivolumab), and for previously treated hepatocellular carcinoma (HCC); and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer. For these types of cancer, cabozantinib has become or is becoming a standard of care. Beyond these approved indications, cabozantinib is currently the focus of a broad clinical development program and is being investigated both alone and in combination with other therapies in a wide variety of cancers.

The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK, approved as part of multiple regimens to treat advanced melanoma and marketed under a collaboration with Genentech, Inc. (a member of the Roche Group) (Genentech); and MINNEBRO® (esaxerenone), an oral, non-steroidal, selective blocker of the mineralocorticoid receptor, approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited (Daiichi Sankyo).

We remain committed to expanding our oncology product pipeline through our drug discovery efforts, which encompass both small molecule and biologics programs with multiple modalities and mechanisms of action.

Basis of Presentation

The accompanying Condensed Consolidated Financial Statements include the accounts of Exelixis and those of our wholly-owned subsidiaries. These entities' functional currency is the U.S. dollar. All intercompany balances and transactions have been eliminated.

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In our opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of our financial statements for the periods presented have been included. Operating results for the three months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021 or for any future period. The accompanying Condensed Consolidated Financial Statements and Notes thereto should be read in conjunction with our Consolidated Financial Statements and Notes thereto for the year ended December 31, 2020, included in our Annual Report on Form 10-K submitted to the SEC on February 10, 2021.

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2021, which is a 52-week fiscal year, will end on December 31, 2021 and fiscal year 2020, which was a 52-week fiscal year, ended on January 1, 2021. For convenience, references in this report as of and for the three months ended April 2, 2021 and April 3, 2020, and as of and for the fiscal year ended January 1, 2021, are indicated as being as of and for the fiscal periods ended March 31, 2021 and March 31, 2020 and the year ended December 31, 2020, respectively.

Segment Information

We operate in one business segment that focuses on the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Our Chief Executive Officer, as the chief operating decision-maker, manages and allocates resources to our operations on a total consolidated basis. Consistent with this decision-making process, our Chief

Executive Officer uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets.

All of our long-lived assets are located in the U.S. See “Note 2. Revenues” for enterprise-wide disclosures about product sales, revenues from major customers and revenues by geographic region.

Use of Estimates

The preparation of the accompanying Condensed Consolidated Financial Statements conforms to accounting principles generally accepted in the U.S., which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenues and expenses, and related disclosures. On an ongoing basis, we evaluate our significant estimates. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Reclassifications

Certain prior period amounts in the accompanying Condensed Consolidated Financial Statements have been reclassified to conform to the current period presentation. Such reclassifications did not impact previously reported total revenues, income from operations, net income, total assets, total liabilities or total stockholders’ equity.

Significant Accounting Policies

Except for the foreign currency forward contracts for non-designated hedges, there have been no material changes to our significant accounting policies during the three months ended March 31, 2021, as compared to the significant accounting policies disclosed in Note 1 – Significant Accounting Policies included in the our Annual Report on Form 10-K for the year ended December 31, 2020.

Foreign Currency Forward Contracts for Non-Designated Hedges

We may use forward foreign currency exchange contracts (forward contracts) to hedge certain operational exposures resulting from potential changes in foreign currency exchange rates. Our strategy is to enter into foreign currency forward contracts so that increases or decreases in our foreign currency exposures are offset by gains or losses on the foreign currency forward contracts thereby mitigating the risks and volatility associated with our foreign currency transactions. We do not apply hedge accounting treatment to these non-designated hedging instruments. We do not hold or issue derivative instruments for trading or speculative purposes.

Our foreign currency forward contracts are generally short-term in duration. Given the short duration of the forward contracts, amounts recorded generally are not significant. We account for our derivative instruments as either assets or liabilities on our Condensed Consolidated Balance Sheets and measure them at fair value. Derivatives not designated as hedging instruments are adjusted to fair value through earnings in other income (expense), net in the Condensed Consolidated Statements of Income.

Recently Adopted Accounting Pronouncements

On January 1, 2021, we adopted the Accounting Standards Board’s (FASB) Accounting Standards Update (ASU) 2019-12, *Income Taxes (Topic 740)-Simplifying the Accounting for Income Taxes* (ASU 2019-12). ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in Accounting Standards Codification (ASC) Topic 740, *Income Taxes* and clarifying and amending existing guidance. Our adoption of ASU 2019-12 did not have a significant impact on the accompanying Condensed Consolidated Financial Statements.

Recent Accounting Pronouncements Not Yet Adopted

There were no new accounting pronouncements issued since our filing of the Annual Report on Form 10-K for the year ended December 31, 2020, which could have a significant effect on our condensed consolidated financial statements.

NOTE 2. REVENUES

Revenues consisted of the following (in thousands):

	Three Months Ended March 31,	
	2021	2020
Product revenues:		
Gross product revenues	$ 314,205	$ 252,566
Discounts and allowances	(86,993)	(58,686)
Net product revenues	227,212	193,880
Collaboration revenues:		
License revenues	27,528	20,879
Collaboration services revenues	15,490	12,156
Total collaboration revenues	43,018	33,035
Total revenues	$ 270,230	$ 226,915

The percentage of total revenues by customer who individually accounted for 10% or more of our total revenues were as follows:

	Three Months Ended March 31,	
	2021	2020
Affiliates of CVS Health Corporation	15 %	18 %
Affiliates of AmerisourceBergen Corporation	14 %	11 %
Affiliates of McKesson Corporation	13 %	15 %
Ipsen Pharma SAS	13 %	13 %
Affiliates of Optum Specialty Pharmacy	9 %	12 %

The percentage of trade receivables by customer who individually accounted for 10% or more of our trade receivables were as follows:

	March 31, 2021	December 31, 2020
Ipsen Pharma SAS	22 %	23 %
Affiliates of McKesson Corporation	18 %	12 %
Affiliates of AmerisourceBergen Corporation	16 %	11 %
Affiliates of CVS Health Corporation	12 %	11 %
Takeda Pharmaceutical Company Limited	5 %	10 %

Revenues by geographic region were as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
U.S.	$ 229,957	$ 196,596
Europe	33,806	29,036
Japan	6,467	1,283
Total revenues	$ 270,230	$ 226,915

Total revenues include net product revenues attributed to geographic regions based on the ship-to location and license and collaboration services revenues attributed to geographic regions based on the location of our collaboration partners' headquarters.

Net product revenues and license revenues are recorded in accordance with ASC Topic 606, *Revenue from Contracts with Customers* (Topic 606). License revenues include the recognition of the portion of milestones payments allocated to the transfer of intellectual property licenses for which it had become probable in the current period that the

milestone would be achieved and a significant reversal of revenues would not occur, as well as royalty revenues and our share of profits under our collaboration agreement with Genentech. Collaboration services revenues were recorded in accordance with ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* and by analogy to Topic 606. Collaboration services revenues include the recognition of deferred revenues for the portion of upfront and milestone payments allocated to our research and development services performance obligations, development cost reimbursements earned under our collaboration agreements, product supply revenues, net of product supply costs, and the royalties we paid to GlaxoSmithKline (GSK) on sales of products containing cabozantinib by our collaboration partners. We received notification that, effective January 1, 2021, Royalty Pharma plc (Royalty Pharma) acquired from GSK all rights, title and interest in royalties on net product sales containing cabozantinib for non-U.S. markets for the full term of the royalty and for the U.S. market through September 2026, after which time U.S. royalties will revert back to GSK.

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

	Three Months Ended March 31,	
	2021	2020
CABOMETYX	$ 223,595	$ 189,216
COMETRIQ	3,617	4,664
Net product revenues	$ 227,212	$ 193,880

Product Sales Discounts and Allowances

The activities and ending reserve balances for each significant category of discounts and allowances, which constitute variable consideration, were as follows (in thousands):

	Chargebacks, Discounts for Prompt Payment and Other	Other Customer Credits/Fees and Co-pay Assistance	Rebates	Total
Balance at December 31, 2020	$ 9,853	$ 3,279	$ 17,404	$ 30,536
Provision related to sales made in:				
Current period	52,470	8,054	25,232	85,756
Prior periods	(27)	(2)	1,266	1,237
Payments and customer credits issued	(49,636)	(5,622)	(15,935)	(71,193)
Balance at March 31, 2021	$ 12,660	$ 5,709	$ 27,967	$ 46,336

The allowance for chargebacks, discounts for prompt payment and other are recorded as a reduction of trade receivables, net and the remaining reserves are recorded as rebates and fees due to customers or as other current liabilities in the accompanying Condensed Consolidated Balance Sheets.

Contract Assets and Liabilities

We receive payments from our collaboration partners based on billing schedules established in each contract. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We may also recognize revenue in advance of the contractual billing schedule and such amounts are recorded as a contract asset when recognized. We may be required to defer recognition of revenue for upfront and milestone payments until we perform our obligations under these arrangements, and such amounts are recorded as deferred revenue upon receipt or when due. For those contracts that have multiple performance obligations, contract assets and liabilities are reported on a net basis at the contract level. Contract assets and liabilities were as follows (in thousands):

	March 31, 2021	December 31, 2020
Contract assets	$ —	$ —
Contract liabilities:		
Current portion[1]	$ 9,207	$ 1,790
Long-term portion[2]	9,760	3,755
Total contract liabilities	$ 18,967	$ 5,545

(1) Presented in other current liabilities in the accompanying Condensed Consolidated Balance Sheets.
(2) Presented in the long-term portion of deferred revenues in the accompanying Condensed Consolidated Balance Sheets.

During the three months ended March 31, 2021 and 2020, we recognized $2.5 million and $1.6 million, respectively, in revenues that were included in the beginning deferred revenues balance for those periods.

During the three months ended March 31, 2021, and 2020, we recognized $27.8 million and $18.8 million, respectively, in revenues for performance obligations satisfied in previous periods. Such revenues were primarily related to royalty payments allocated to the license performance obligations for our collaborations with Ipsen Pharma SAS (Ipsen), Takeda Pharmaceutical Company Limited (Takeda), Daiichi Sankyo Company, Limited (Daiichi Sankyo) and Genentech Inc. (a member of the Roche Group) (Genentech).

As of March 31, 2021, $87.3 million of the combined transaction prices for our Ipsen and Takeda collaborations were allocated to performance obligations that had not yet been satisfied. See “Note 3. Collaboration Agreements - Cabozantinib Collaborations - Performance Obligations and Transaction Prices for our Ipsen and Takeda Collaborations” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2020 for information about the expected timing to satisfy these performance obligations.

NOTE 3. COLLABORATION AGREEMENTS AND IN-LICENSING ARRANGEMENTS

We have established multiple collaborations with leading pharmaceutical companies for the commercialization and further development of our cabozantinib franchise. Additionally, we have entered into several research collaborations and in-licensing arrangements to further enhance our early-stage pipeline and expand our ability to discover, develop and commercialize novel therapies with the goal of providing new treatment options for cancer patients and their physicians. We also entered into other collaborations with leading pharmaceutical companies for other compounds and programs in our portfolio.

See “Note 3. Collaboration Agreements” to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2020, or as further described below, for additional information on each of our collaboration agreements and in-licensing arrangements.

Cabozantinib Collaborations

Ipsen Collaboration

In February 2016, we entered into a collaboration agreement with Ipsen for the commercialization and further development of cabozantinib. Under the terms of the collaboration agreement, as amended, Ipsen received exclusive commercialization rights for current and potential future cabozantinib indications outside of the U.S. and Japan. We have also agreed to collaborate with Ipsen on the development of cabozantinib for current and potential future indications. The parties’ efforts are governed through a joint steering committee and appropriate subcommittees established to guide and oversee the collaboration’s operation and strategic direction; provided, however, that we retain final decision-making authority with respect to cabozantinib’s ongoing development.

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

	Three Months Ended March 31,	
	2021	2020
License revenues	$ 22,451	$ 17,949
Collaboration services revenues	11,355	11,087
Total	$ 33,806	$ 29,036

As of March 31, 2021, $44.8 million of the transaction price was allocated to our research and development services performance obligations that has not yet been satisfied.

Takeda Collaboration

In January 2017, we entered into a collaboration and license agreement with Takeda, which was subsequently amended effective March 2018, May 2019 and September 2020 to, among other things, modify the amount of reimbursements we are eligible to receive for costs associated with our required pharmacovigilance activities, modify the amount of milestones we are eligible to receive, and modify certain cost sharing obligations related to the Japan-specific development costs associated with CONTACT-01 and CONTACT-02 clinical trials. Pursuant to this collaboration and license agreement, as amended, Takeda has exclusive commercialization rights for current and potential future cabozantinib indications in Japan, and the parties have agreed to collaborate on the clinical development of cabozantinib in Japan. The operation and strategic direction of the parties' collaboration is governed through a joint executive committee and appropriate subcommittees.

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

	Three Months Ended March 31,	
	2021	2020
License revenues	$ 1,301	$ —
Collaboration services revenues	4,135	1,069
Total	$ 5,436	$ 1,069

As of March 31, 2021, $42.5 million of the transaction price was allocated to our research and development services performance obligations that has not yet been satisfied.

GSK & Royalty Pharma

In October 2002, we established a product development and commercialization collaboration agreement with GSK, that required us to pay a 3% royalty to GSK on the worldwide net sales of any product incorporating cabozantinib by us and our collaboration partners. As disclosed in Note 2, we received notification that, effective January 1, 2021, Royalty Pharma acquired from GSK all rights, title and interest in royalties on net product sales containing cabozantinib for non-U.S. markets for the full term of the royalty and for the U.S. market through September 2026, after which time U.S. royalties will revert back to GSK. Royalties earned by GSK and Royalty Pharma in connection with our sales of cabozantinib are included in cost of goods sold and as a reduction of collaboration services revenues for sales by our collaboration partners. Such royalties were $10.1 million and $8.1 million during the three months ended March 31, 2021 and 2020, respectively.

Genentech Collaboration

In December 2006, we out-licensed the development and commercialization of cobimetinib to Genentech under a worldwide collaboration agreement. In November 2015, the U.S. Food and Drug Administration (FDA) approved cobimetinib, under the brand name COTELLIC, in combination with Genentech's ZELBORAF® (vemurafenib) for the treatment of patients with BRAF V600E or V600K mutation-positive advanced melanoma. COTELLIC in combination with ZELBORAF has also been approved in the European Union and multiple additional countries for use in the same indication. In July 2020, the FDA also approved COTELLIC for use in combination with ZELBORAF and TECENTRIQ® (atezolizumab) for the treatment of patients with BRAF V600 mutation-positive advanced melanoma in previously untreated patients. License revenues under the collaboration agreement with Genentech were as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Profits on U.S. commercialization	$ 1,794	$ 1,407
Royalty revenues on ex-U.S. sales	$ 951	$ 1,309

Research Collaborations and In-Licensing Arrangements

In the first quarter of 2021, we entered into additional licensing and collaboration agreements in support of our preclinical pipeline with Adagene, Inc. (Adagene) and WuXi Biologics Ireland Ltd (WuXi Bio). As part of these agreements we made aggregate upfront payments of $14.0 million in exchange for licenses to develop and commercialize products. We committed to make payments to Adagene for potential future development milestones of $55.0 million, regulatory milestones of $200.0 million, and commercial milestones of $525.0 million, each in the aggregate, as well as royalties on future net product sales. We also committed to make payments to WuXi Bio for potential future development milestones of $18.5 million, regulatory milestones of $30.0 million, and commercial milestones of $80.0 million, each per product, as well as royalties on future net product sales.

NOTE 4. CASH AND INVESTMENTS

Cash, Cash Equivalents and Restricted Cash Equivalents

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

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 370,209	$ 319,217
Restricted cash equivalents included in other long-term assets	49,712	1,555
Cash, cash equivalents, and restricted cash equivalents as reported in the accompanying Condensed Consolidated Statements of Cash Flows	$ 419,921	$ 320,772

Restricted cash equivalents are used to collateralize letters of credit and consist of money-market funds and certificates of deposit with original maturities of 90 days or less. The restricted cash equivalents are classified as other long-term assets based upon the remaining term of the underlying restriction. As of March 31, 2021, restricted cash equivalents included $48.2 million of short-term investments as collateral under our standby letter of credit entered into in January 2021 as guarantee of our obligation to fund our portion of the total tenant improvements related to our build-to-suit lease at our corporate campus.

Cash, Cash Equivalents, Restricted Cash Equivalents and Investments

Cash, cash equivalents, restricted cash equivalents and investments consisted of the following (in thousands):

	March 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 667,071	$ 219	$ (1)	$ 667,289
Corporate bonds	495,490	3,609	(275)	498,824
U.S. Treasury and government-sponsored enterprises	148,208	83	(7)	148,284
Municipal bonds	27,776	64	(8)	27,832
Total debt securities available-for-sale	1,338,545	3,975	(291)	1,342,229
Cash	52,757	—	—	52,757
Money market funds	105,775	—	—	105,775
Certificates of deposit	63,305	—	—	63,305
Total cash, cash equivalents, restricted cash equivalents and investments	$ 1,560,382	$ 3,975	$ (291)	$ 1,564,066

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 569,456	$ 372	$ —	$ 569,828
Corporate bonds	543,520	5,244	(7)	548,757
U.S. Treasury and government-sponsored enterprises	208,326	232	(4)	208,554
Municipal bonds	28,680	83	(1)	28,762
Total debt securities available-for-sale	1,349,982	5,931	(12)	1,355,901
Cash	82,176	—	—	82,176
Money market funds	40,761	—	—	40,761
Certificates of deposit	60,004	—	—	60,004
Total cash, cash equivalents, restricted cash equivalents and investments	$ 1,532,923	$ 5,931	$ (12)	$ 1,538,842

Interest receivable was $3.6 million and $4.5 million as of March 31, 2021 and December 31, 2020, respectively, and is included in prepaid expenses and other current assets in the accompanying Condensed Consolidated Balance Sheets.

Realized gains and losses on the sales of investments were insignificant during the three months ended March 31, 2021 and 2020.

We manage credit risk associated with our investment portfolio through our investment policy, which limits purchases to high-quality issuers and limits the amount of our portfolio that can be invested in a single issuer. The fair value and gross unrealized losses on debt securities available-for-sale in an unrealized loss position were as follows (in thousands):

	March 31, 2021	
	Fair Value	Gross Unrealized Losses
Commercial paper	$ 4,722	$ (1)
Corporate bonds	131,468	(275)
U.S. Treasury and government-sponsored enterprises	31,981	(7)
Municipal bonds	12,120	(8)
Total	$ 180,291	$ (291)

	December 31, 2020	
	Fair Value	Gross Unrealized Losses
Corporate bonds	$ 28,445	$ (7)
U.S. Treasury and government-sponsored enterprises	21,989	(4)
Municipal bonds	5,865	(1)
Total	$ 56,299	$ (12)

All securities presented have been in an unrealized loss position for less than 12 months. There were 53 and 14 investments in an unrealized loss position as of March 31, 2021 and December 31, 2020, respectively. During the three months ended March 31, 2021 and 2020, we did not record an allowance for credit losses or other impairment charges on our investment securities. Based upon our quarterly impairment review, we determined that the unrealized losses were not attributed to credit risk but were primarily associated with changes in interest rates and market liquidity. Based on the scheduled maturities of our investments, we determined that it was more likely than not that we will hold these investments for a period of time sufficient for a recovery of our cost basis.

The fair value of debt securities available-for-sale by contractual maturity was as follows (in thousands):

	March 31, 2021	December 31, 2020
Maturing in one year or less	$ 1,021,369	$ 1,034,150
Maturing after one year through five years	320,860	321,751
Total debt securities available-for-sale	$ 1,342,229	$ 1,355,901

NOTE 5. FORWARD CURRENCY CONTRACTS

In January 2021, we initiated an operational hedging program and entered into forward contracts to hedge certain operational exposures for the changes in foreign currency exchanges rates associated with assets or liabilities denominated in foreign currencies, primarily the Euro.

As of March 31, 2021, we had one forward contract outstanding to sell €9.3 million. The forward contract has a maturity of three months, is recorded at fair value and is included in prepaid expenses and other current assets in the Condensed Consolidated Balance Sheets. The fair value of the forward contract at March 31, 2021 was not material. The forward contract is considered a Level 2 in the fair value hierarchy of our fair value measurements. For the three months ended March 31, 2021, we recognized $0.4 million of gains on the maturity of our forward contracts, which is included in other income (expense), net on our Condensed Consolidated Statements of Income.

NOTE 6. FAIR VALUE MEASUREMENTS

Fair value reflects the amounts that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy has the following three levels:

- Level 1 - quoted prices (unadjusted) in active markets for identical assets and liabilities;
- Level 2 - inputs other than level 1 that are observable either directly or indirectly, such as quoted prices in active markets for similar instruments or on industry models using data inputs, such as interest rates and prices that can be directly observed or corroborated in active markets;
- Level 3 - unobservable inputs that are supported by little or no market activity that are significant to the fair value measurement

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

	March 31, 2021		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 667,289	$ 667,289
Corporate bonds	—	498,824	498,824
U.S. Treasury and government-sponsored enterprises	—	148,284	148,284
Municipal bonds	—	27,832	27,832
Total debt securities available-for-sale	—	1,342,229	1,342,229
Money market funds	105,775	—	105,775
Certificates of deposit	—	63,305	63,305
Total financial assets carried at fair value	$ 105,775	$ 1,405,534	$ 1,511,309

	December 31, 2020		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 569,828	$ 569,828
Corporate bonds	—	548,757	548,757
U.S. Treasury and government-sponsored enterprises	—	208,554	208,554
Municipal bonds	—	28,762	28,762
Total debt securities available-for-sale	—	1,355,901	1,355,901
Money market funds	40,761	—	40,761
Certificates of deposit	—	60,004	60,004
Total financial assets carried at fair value	$ 40,761	$ 1,415,905	$ 1,456,666

When available, we value investments based on quoted prices for those financial instruments, which is a Level 1 input. Our remaining investments are valued using third-party pricing sources, which use observable market prices, interest rates and yield curves observable at commonly quoted intervals for similar assets as observable inputs for pricing, which is a Level 2 input.

The carrying amount of our remaining financial assets and liabilities, which include cash, receivables and payables, approximate their fair values due to their short-term nature.

NOTE 7. INVENTORY

Inventory consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Raw materials	$ 7,988	$ 7,773
Work in process	21,873	20,610
Finished goods	5,786	7,291
Total	$ 35,647	$ 35,674
Balance Sheet classification:		
Current portion included in inventory	$ 24,757	$ 20,973
Long-term portion included in other long-term assets	10,890	14,701
Total	$ 35,647	$ 35,674

Write-downs related to excess and expiring inventory were $2.1 million and $0.2 million for the three months ended March 31, 2021 and 2020, respectively.

NOTE 8. STOCK-BASED COMPENSATION

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

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 12,396	$ 5,086
Selling, general and administrative	22,257	8,896
Total stock-based compensation expense	$ 34,653	$ 13,982

Stock-based compensation for each type of award under our equity incentive plans and ESPP were as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Stock options	$ 4,694	$ 4,994
Restricted stock units	11,669	7,797
Performance stock units	17,947	496
ESPP	343	695
Total stock-based compensation expense	$ 34,653	$ 13,982

As of March 31, 2021, 9,272,614 shares were available for grant under the Exelixis, Inc. 2017 Equity Incentive Plan (as amended and restated, the 2017 Plan). The share reserve is reduced by 1 share for each share issued pursuant to a stock option and 1.5 shares for full value awards granted in the form of restricted stock units (RSUs).

During the three months ended March 31, 2021, we granted 881,440 stock options with a weighted average exercise price of $21.75 per share and a weighted average grant date fair value of $9.88 per share. As of March 31, 2021, there were 15,688,044 stock options outstanding and $30.7 million of related unrecognized compensation expense.

During the three months ended March 31, 2021, we granted 3,059,698 service-based restricted stock units (RSUs) with a weighted average grant date fair value of $21.43 per share. As of March 31, 2021, there were 8,282,867 RSUs outstanding and $155.9 million of related unrecognized compensation expense.

Stock options and RSUs granted to employees during the three months ended March 31, 2021 have vesting conditions and contractual lives of a similar nature to those described in “Note 8. Employee Benefit Plans” of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

In March 2021, we awarded 1,027,650 (the target amount) performance-based restricted stock units (PSUs), subject to a performance and a market condition (the 2021 PSUs). Pursuant to the terms of 2021 PSUs, the holders of the awards may earn up to 200% of the target amount of shares, depending on the level of achievement of the performance condition related to certain net product revenues and a total shareholder return (TSR) market condition. The TSR market condition is based on our relative TSR percentile rank compared to companies in the NASDAQ Biotechnology Index during the performance period, which is January 2, 2021 through December 29, 2023. Fifty percent of the shares earned subject to the performance and market conditions will vest at the end of the performance period and the remainder will vest approximately one year later subject to employee’s continuous service. The 2021 PSUs will be forfeited if the performance condition at or above a threshold level is not achieved by December 29, 2023.

A Monte Carlo simulation model was used to determine the grant date fair value of $24.54 for the 2021 PSUs based on the following assumptions:

Fair value of the Company’s common stock on grant date	$ 21.31
Expected volatility	49 %
Risk-free interest rate	0.29 %
Dividend yield	— %

The Monte Carlo simulation model also assumed correlations of returns of the stock prices of the Company’s common stock and the common stock of a peer group of companies and historical stock price volatility of the peer group of companies. The valuation model also used terms based on the length of the performance period and compound annual growth rate goals for total stockholder return based on the provisions of the award.

As of March 31, 2021, there were 8,767,305 PSUs outstanding and $161.2 million of related unrecognized compensation expense. Expense recognition for PSUs commences when it is determined that achievement of the performance target is probable. During the three months ended March 31, 2021, we achieved additional performance targets for 461,532 additional PSUs granted during 2019. For more information about our PSUs, see “Note 8. Employee Benefit Plans” of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

NOTE 9. PROVISION FOR (BENEFIT FROM) INCOME TAXES

The effective tax rate for the three months ended March 31, 2021 differed from the U.S. federal statutory tax rate of 21% primarily due to excess tax benefits related to the exercise of certain stock options, in relation to the generation of a small pre-tax loss during the period. The effective tax rate for the three months ended March 31, 2020 differed from U.S. federal statutory tax rate of 21% primarily due to excess tax benefits related to the exercise of certain stock options during the period and the generation of federal tax credits.

NOTE 10. NET INCOME PER SHARE

Net income per share - basic and diluted, were computed as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2021	2020
Numerator:		
Net income	$ 1,601	$ 48,612
Denominator:		
Weighted-average common shares outstanding — basic	312,473	305,388
Dilutive securities	8,814	10,451
Weighted-average common shares outstanding — diluted	321,287	315,839
Net income per share — basic	$ 0.01	$ 0.16
Net income per share — diluted	$ 0.00	$ 0.15

Dilutive securities included outstanding stock options and PSOs, unvested RSUs and PSUs and ESPP contributions.

Certain potential common shares were excluded from our calculation of weighted-average common shares outstanding - diluted because either they would have had an anti-dilutive effect on net income per share or they were related to shares from PSUs that were contingently issuable and the contingency had not been satisfied at the end of the reporting period. The weighted-average potential common shares excluded from our calculation were as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Anti-dilutive securities and contingently issuable shares excluded	10,007	12,014

NOTE 11. COMMITMENTS AND CONTINGENCIES

In September 2019, we received a notice letter regarding an Abbreviated New Drug Application (ANDA) submitted to the FDA by MSN Pharmaceuticals, Inc. (MSN), requesting approval to market a generic version of CABOMETYX tablets. MSN's initial notice letter included a Paragraph IV certification with respect to our U.S. Patent Nos. 8,877,776, 9,724,342, 10,034,873 and 10,039,757, which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book. MSN's initial notice letter did not provide a Paragraph IV certification against U.S. Patent No. 7,579,473, the composition of matter patent, or U.S. Patent No. 8,497,284, a method of use patent. On October 29, 2019, we filed a complaint in the United States District Court for the District of Delaware for patent infringement against MSN asserting U.S. Patent No. 8,877,776 arising from MSN's ANDA filing with the FDA. On November 20, 2019, MSN filed its response to the complaint, alleging that U.S. Patent No. 8,877,776 is invalid and not infringed. On May 5, 2020, we received notice from MSN that it had amended its ANDA to assert additional Paragraph IV certifications. The ANDA now requests approval to market a generic version of CABOMETYX tablets prior to expiration of the two previously unasserted CABOMETYX patents: U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284. On May 11, 2020, we filed a complaint in the United States District Court for the District of Delaware for patent infringement against MSN asserting U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284 arising from MSN's amended ANDA filing with the FDA. Neither of our complaints alleges infringement of U.S. Patent Nos. 9,724,342, 10,034,873 and 10,039,757. On May 22, 2020, MSN filed its response to the complaint, alleging that each of U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284 is invalid and not infringed. On March 23, 2021, MSN filed its First Amended Answer and Counterclaims (amending its prior filing from May 22, 2020), seeking, among other things, a declaratory judgment that U.S. Patent No. 9,809,549 is invalid and would not be infringed by

MSN if its generic version of CABOMETYX tablets were approved by the FDA. On April 7, 2021, we filed our response to MSN's First Amended Answer and Counterclaims, denying, among other things, that U.S. Patent No. 9,809,549 is invalid or would not be infringed. In our complaints, we are seeking, among other relief, an order that the effective date of any FDA approval of the ANDA would be a date no earlier than the expiration of all of U.S. Patent No. 7,579,473, U.S. Patent No. 8,497,284 and U.S. Patent No. 8,877,776, the latest of which expires on October 8, 2030, and equitable relief enjoining MSN from infringing these patents. These lawsuits against MSN have been consolidated, and a bench trial has been scheduled for May 2022.

In May 2021, we received a notice letter from Teva Pharmaceuticals USA, Inc. (Teva) regarding an ANDA Teva submitted to the FDA, requesting approval to market a generic version of CABOMETYX tablets. Teva's notice letter included a Paragraph IV certification with respect to our U.S. Patent Nos. 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which are listed in the Orange Book and expire in 2033, 2031 and 2031, respectively. Teva's notice letter did not provide a Paragraph IV certification against any additional CABOMETYX patents. We are reviewing the details of the Paragraph IV certification notice.

The sale of any generic version of CABOMETYX earlier than its patent expiration could significantly decrease our revenues derived from the U.S. sales of CABOMETYX and thereby materially harm our business, financial condition and results of operations. It is not possible at this time to determine the likelihood of an unfavorable outcome or estimate of the amount or range of any potential loss.

We may also from time to time become a party or subject to various other legal proceedings and claims, either asserted or unasserted, which arise in the ordinary course of business. Some of these proceedings have involved, and may involve in the future, claims that are subject to substantial uncertainties and unascertainable damages.

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

This Quarterly Report on Form 10-Q contains forward-looking statements. These statements are based on Exelixis, Inc.'s (Exelixis, we, our or us) current expectations, assumptions, estimates and projections about our business and our industry and involve known and unknown risks, uncertainties and other factors that may cause our company's or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, as well as those discussed elsewhere in this report. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

This discussion and analysis should be read in conjunction with our condensed consolidated financial statements and accompanying notes included in this report and the consolidated financial statements and accompanying notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 submitted to the Securities and Exchange Commission (SEC) on February 10, 2021.

Overview

We are an oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Since we were founded in 1994, four products resulting from our discovery efforts have progressed through clinical development, received regulatory approval and established a commercial presence in various geographies around the world. Two are derived from cabozantinib, our flagship molecule, an inhibitor of multiple tyrosine kinases including MET, AXL, VEGF receptors and RET. Our cabozantinib products are: CABOMETYX® (cabozantinib) tablets approved for advanced renal cell carcinoma (RCC), both alone and in combination with Bristol-Myers Squibb Company's (BMS) OPDIVO® (nivolumab), and for previously treated hepatocellular carcinoma (HCC); and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer (MTC). For these types of cancer, cabozantinib has become or is becoming a standard of care.

The other two products resulting from our discovery efforts are: COTELLIC® (cobimetinib), an inhibitor of MEK, approved as part of multiple combination regimens to treat specific forms of advanced melanoma and marketed under a collaboration with Genentech, Inc. (a member of the Roche Group) (Genentech); and MINNEBRO® (esaxerenone), an oral,

non-steroidal, selective blocker of the mineralocorticoid receptor, approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited (Daiichi Sankyo).

The U.S. Food and Drug Administration (FDA) first approved CABOMETYX for previously treated patients with advanced RCC in April 2016, and in December 2017 the FDA expanded CABOMETYX's approval to include previously untreated patients with advanced RCC. Additionally, in January 2019, the FDA approved CABOMETYX for the treatment of patients with HCC who have been previously treated with sorafenib. Most recently on January 22, 2021, the FDA approved CABOMETYX in combination with OPDIVO as a first-line treatment of patients with advanced RCC.

To develop and commercialize CABOMETYX and COMETRIQ outside the U.S., we have entered into license agreements with Ipsen Pharma SAS (Ipsen) and Takeda Pharmaceutical Company Limited (Takeda). We granted to Ipsen the rights to develop and commercialize cabozantinib outside of the U.S. and Japan, and to Takeda the rights to develop and commercialize cabozantinib in Japan. Both Ipsen and Takeda also contribute financially and operationally to the further global development and commercialization of the cabozantinib franchise in other potential indications, and we continue to work closely with them on these activities. Utilizing its regulatory expertise and established international oncology marketing network, Ipsen has continued to execute on its commercialization plans for CABOMETYX, having received regulatory approvals and launched in multiple territories outside of the U.S., including in the European Union (EU) and Canada, as a treatment for advanced RCC and for HCC in adults who have previously been treated with sorafenib. In addition, in March 2021, Ipsen and BMS received regulatory approval from the European Commission (EC) for CABOMETYX in combination with OPDIVO as a first-line treatment for patients with advanced RCC , and both Ipsen and BMS plan to submit applications to approve the combination in other territories beyond the EU. With respect to the Japanese market, Takeda has received Manufacturing and Marketing Approvals from the Japanese Ministry of Health, Labour and Welfare (MHLW) of CABOMETYX as a treatment of patients with curatively unresectable or metastatic RCC and as a treatment of patients with unresectable HCC who progressed after cancer chemotherapy. In October 2020, Takeda and Ono Pharmaceutical Co., Ltd. (Ono), BMS' development and commercialization partner in Japan, submitted a supplemental application to the Japanese MHLW for Manufacturing and Marketing Approval of CABOMETYX in combination with OPDIVO for the treatment of patients with unresectable, advanced or metastatic RCC.

In addition to our regulatory and commercialization efforts in the U.S. and the support provided to our collaboration partners for rest-of-world regulatory and commercialization activities, we are also pursuing other indications for cabozantinib that have the potential to increase the number of cancer patients who could benefit from this medicine. We are evaluating cabozantinib, both as a single agent and in combination with other therapies, in a broad development program comprising over 100 ongoing or planned clinical trials across multiple indications. We, along with our collaboration partners, sponsor some of the trials, and independent investigators conduct the remaining trials through our Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP) or our investigator-sponsored trial program. Informed by the available data from these clinical trials, we continue to advance the development program for the cabozantinib franchise with potentially label-enabling trials. One pivotal trial that has resulted from this effort is COSMIC-311, our ongoing phase 3 pivotal trial evaluating cabozantinib versus placebo in patients with radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC) who have progressed after up to two VEGF receptor-targeted therapies. In December 2020, we announced that COSMIC-311 had met its co-primary endpoint of demonstrating significant improvement in progression-free survival (PFS), and in February 2021, we announced the FDA had granted Breakthrough Therapy Designation to cabozantinib as a potential treatment for patients with RAI-refractory DTC who have progressed following prior therapy. We intend to discuss the study results, proposed changes to the study conduct, as well as plans for filing an sNDA with the FDA in 2021.

We are particularly interested in continuing to evaluate cabozantinib's potential in combination with immune checkpoint inhibitors (ICIs) to determine if these combinations further improve outcomes for patients. Building on preclinical and clinical observations that cabozantinib may promote a more immune-permissive tumor environment potentially resulting in cooperative activity of cabozantinib in combination with these products, we are evaluating cabozantinib in combination with a variety of ICIs. CheckMate -9ER, a phase 3 pivotal trial evaluating the combination of cabozantinib and nivolumab compared to sunitinib in previously untreated advanced or metastatic RCC, for which we and our collaboration partner BMS announced positive top-line results in April 2020, is reflective of this strategy. The trial met its primary endpoint of PFS at final analysis, as well as the secondary endpoints of overall survival (OS) at a pre-specified interim analysis and objective response rate (ORR), and showed that the combination of cabozantinib with nivolumab significantly improved the three key efficacy outcomes as compared with sunitinib, doubling PFS and ORR and reducing the risk of disease progression or death by 40 percent compared with sunitinib. Data from CheckMate -9ER served as the basis for the FDA's and EC's approval of CABOMETYX in combination with OPDIVO as a first-line treatment of patients with advanced RCC in January 2021 and March 2021, respectively. We are also collaborating with BMS on COSMIC-313, a phase 3

pivotal trial evaluating the triplet combination of cabozantinib, nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC. Enrollment for COSMIC-313 was completed in March 2021, and we expect to report top-line results of the event-driven analyses from the trial in 2022.

In an effort to expand our exploration of combinations with ICIs, we have also initiated multiple trials evaluating cabozantinib in combination with F. Hoffmann-La Roche Ltd.'s (Roche) ICI, atezolizumab. COSMIC-312 is a phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab versus sorafenib in previously untreated advanced HCC, for which we announced in August 2020 that enrollment was completed. Based on current event rates, we anticipate announcing top-line results in the second quarter of 2021, and if the data are supportive, we anticipate filing a supplemental New Drug Application (sNDA) with the FDA in the second half of 2021. COSMIC-021 is a broad phase 1b study evaluating the safety and tolerability of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic solid tumors. Based on continuing encouraging efficacy and safety data certain cohorts have been or may be further expanded, including the cohorts of patients with non-small cell lung cancer (NSCLC) who have been previously treated with an ICI and metastatic castration-resistant prostate cancer (mCRPC) who have been previously treated with enzalutamide and/or abiraterone acetate and experienced radiographic disease progression in soft tissue. We anticipate completing enrollment of up to 1,732 patients in the trial in the first half of 2021, although both the timing and final number of patients are subject to the initiation of additional cohorts or expansion of selected existing cohorts, as well as any further delays resulting from the COVID-19 pandemic. Since the initiation of the trial, data from COSMIC-021 have been instrumental in guiding our clinical development strategy for cabozantinib in combination with ICIs, including supporting the initiation of COSMIC-312, and three phase 3 pivotal trials in collaboration with Roche, CONTACT-01, CONTACT-02 and CONTACT-03, evaluating the combination of cabozantinib with atezolizumab in patients with metastatic NSCLC, mCRPC and advanced RCC, respectively. Based on regulatory feedback from the FDA, and if supported by the clinical data, we intend to file with the FDA for accelerated approval in an mCRPC indication in 2021.

We remain committed to expanding our oncology product pipeline through drug discovery efforts, which encompass both small molecule and biologics programs with multiple modalities and mechanisms of action. Our small molecule discovery programs are supported by a robust and expanding infrastructure, including a library of 4.6 million compounds. We have extensive experience in the identification and optimization of drug candidates against multiple target classes for oncology, inflammation and metabolic diseases. The first compound to advance from our recent drug discovery efforts is XL092, a next-generation oral tyrosine kinase inhibitor that targets VEGF receptors, MET, AXL, MER and other kinases implicated in cancer's growth and spread. In designing XL092, we sought to build upon our experience with cabozantinib, retaining the target profile of cabozantinib while improving key characteristics, including the pharmacokinetic half-life. We are currently evaluating XL092 in STELLAR-001, a phase 1b clinical trial in patients with advanced solid tumors, for which dose-escalation cohorts evaluating the compound, both as a single agent and in combination with atezolizumab, are currently enrolling, and we expect the trial will begin to enroll patients in additional dose-escalation cohorts evaluating XL092 in combination with avelumab, an ICI developed by Merck KGaA, Darmstadt, Germany (Merck KGaA) and Pfizer Inc. (Pfizer), during the second quarter of 2021. We expect that once recommended doses of both single-agent XL092 and XL092 in combination with atezolizumab or avelumab are established, the trial will begin to enroll expansion cohorts for patients with clear cell and non-clear cell RCC, hormone-receptor positive breast cancer, mCRPC and urothelial carcinoma (UC).

We also augment our internal small molecule discovery activities through research collaborations and in-licensing arrangements with other companies engaged in small molecule discovery. The most advanced compound to emerge from these arrangements is XL102 (formerly AUR102), the lead program targeting cyclin-dependent kinase 7 under our collaboration with Aurigene Discovery Technologies Limited (Aurigene). In December 2020, based on encouraging preclinical data, we exercised our exclusive option to license XL102 from Aurigene. Following the FDA's acceptance of our Investigational New Drug (IND) application in December 2020, we initiated a phase 1 clinical trial of the compound in January 2021.

Beyond small molecules, we have additionally launched rigorous efforts to discover and advance biologic drug candidates, such as bispecific antibodies, antibody drug conjugates (ADCs) and other innovative biologics that have the potential to become anti-cancer therapies. To facilitate the growth of these biologics programs, we have established multiple research collaborations and in-licensing arrangements, expanding our access to antibodies or other binders, which are the starting point for use with additional technology platforms that we employ to generate next-generation ADCs or bispecific antibodies. Most recently, we entered into a collaboration and license agreement with Adagene Inc. (Adagene), focused on using Adagene's SAFEbody™ technology to develop novel masked ADCs or other innovative biologics with potential for improved therapeutic index, as well as an exclusive license agreement with WuXi Biologics Ireland Limited, a

wholly owned subsidiary of WuXi Biologics (Cayman) Inc. (individually and collectively referred to as WuXi Bio), focused on leveraging WuXi Bio's panel of monoclonal antibodies (mAbs) for the development of ADC, bispecific and certain other novel tumor-targeting biologics applications. We have already made significant progress under our biologics-focused research collaborations and in-licensing arrangements and believe we will continue to do so during the remainder of 2021. For example, based on promising preclinical data for XB002 (formerly known as ICON-2), the lead Tissue Factor ADC program under our research collaboration with Iconic Therapeutics, Inc. (Iconic), we exercised our exclusive option to license XB002 in December 2020. Following the FDA's acceptance of our IND in April 2021, we expect to initiate a phase 1 clinical trial of XB002 during the second quarter of 2021. Also, in May 2021, we executed an asset purchase agreement with GamaMabs Pharma SA (GamaMabs), under which we will, upon the closing of the asset purchase and subject to certain conditions, acquire all rights, title and interest in GamaMabs' antibody program directed at anti-Müllerian hormone receptor 2 (AMHR2), a novel oncology target with relevance in multiple forms of cancer.

We will continue to engage in business development initiatives aimed at acquiring and in-licensing promising oncology platforms and assets and then further characterize and develop them utilizing our established preclinical and clinical development infrastructure. In total, we are advancing drug candidates across approximately 20 ongoing discovery programs toward and through preclinical development, and subject to preclinical data, we have the potential to submit multiple INDs later in 2021.

COVID-19 Update

As of the date of this Quarterly Report, the COVID-19 pandemic continues to have a modest impact on our business operations, in particular on our clinical trial, drug discovery and commercial activities. We have and continue to undertake considerable efforts to mitigate the various problems presented by this crisis, including as described below:

Clinical Trials. To varying degrees and at different rates across our clinical trials, we experienced declines in screening and enrollment activity during the early days of the COVID-19 pandemic, as well as delays in new site activations and restrictions on the access to treatment sites that is necessary to monitor clinical study progress and administration. Beginning during the second quarter of 2020 and throughout the rest of 2020 and the first quarter of 2021, however, that trend reversed, and screening and enrollment activity began to increase. As a result, we and our collaboration partners, including principal investigators and personnel at clinical trial sites, have been successful overall in preventing material delays to our ongoing and planned clinical trials due to the COVID-19 pandemic. We have done this through ongoing assessment of the COVID-19 pandemic's impact and, wherever possible, taking proactive steps in compliance with guidance issued by the FDA, EMA and other regulatory agencies to support the safety of our patients and their access to treatment, as well as to maintain the high quality of our clinical trials. We recognize, however, that we may have to make further operational adjustments to our ongoing and planned clinical trials and that patient enrollment, and new clinical trial site initiations may be further slowed due to the COVID-19 pandemic, especially if it is further prolonged or grows in severity.

Drug Discovery and Preclinical Development. We have partially resumed internal drug discovery in our laboratories following a temporary suspension of these activities while we observed the shelter in place orders issued by the State of California and Alameda County. While this temporary suspension did not result in any significant changes to the timelines for our late-stage discovery work, we did experience modest delays in the advancement of certain of our early-stage programs. We also experienced some modest delays with respect to the portion of drug discovery work outsourced to third-party contractors in regions first impacted by COVID-19. However, those service providers have resumed discovery work and are meeting their contractual obligations in accordance with planned timelines. With respect to the preclinical development work outsourced to third-party contractors, to date that work has continued without substantial delay or interference resulting from the COVID-19 pandemic.

Commercial Activities. Our field employees have partially resumed their in-person promotional activities while supplementing these activities with telephonic and virtual interactions. These efforts enabled them to remain engaged with healthcare professionals and to be available to them as an informational resource. Overall, despite the challenges posed by the COVID-19 pandemic, we believe our commercial business has been only modestly impacted. We believe this is the case largely because of the gravity of the cancer conditions that our products are indicated to treat and because CABOMETYX has been available in the U.S. since 2016, which means its safety and efficacy profile is well known to most healthcare professionals that treat the conditions for which it is indicated.

Supply Chain. We have not experienced production delays or seen any significant impairment to our supply chain as a result of the COVID-19 pandemic. In addition, we continue to maintain substantial safety stock inventories for

our commercial drug substance and drug products, which should be sufficient to maintain robust long-term supply. We continue to work closely with our third-party contract manufacturers, distributors, suppliers, comparator drug sourcing vendors and collaboration partners to safeguard both the timely production and delivery of our products.

General Business Operations. We have taken numerous temporary precautions to help mitigate the risk of transmission of the virus, including reducing the number of our employees working on-site at our Alameda headquarters under enhanced safety and social distancing protocols and initiating an on-site testing program. Although having most of our employees continue to work remotely has required that we devise new ways of working and collaborating, to date, the COVID-19 pandemic has only had a modest impact on our productivity and has not caused significant interruptions in our general business operations. For a discussion of workplace safety measures we have taken as a result of the COVID-19 pandemic, see "Business—Environmental, Health and Safety—Workplace Safety Measures in Response to COVID-19" in Part I, Item 1 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, submitted to the SEC on February 10, 2021.

The circumstances surrounding the COVID-19 pandemic are volatile and subject to rapid change. Despite our mitigation efforts, we may experience delays or an inability to execute on our clinical and preclinical development plans, reduced revenues or other adverse impacts to our business, which are described in more detail in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. We recognize that this pandemic will continue to present unique challenges for us throughout 2021, and potentially into 2022.

First Quarter 2021 Business Updates and Financial Highlights

During the first quarter of 2021, we continued to execute on our business objectives, generating significant revenues from operations and enabling us to continue to seek to maximize the clinical and commercial potential of our products and expand our product pipeline. Significant business updates and financial highlights for the quarter and subsequent to quarter-end include:

Business Updates

- In January 2021, the FDA approved the combination of CABOMETYX and OPDIVO as a first-line treatment of patients with advanced RCC, and we commenced the commercial launch of the combination upon such approval. The approval was based on positive results from the phase 3 pivotal trial, CheckMate -9ER, in which the combination met its primary endpoint of significantly improving PFS at final analysis, as well as the secondary endpoints of OS at a pre-specified interim analysis and ORR, versus sunitinib.
- In January 2021, we announced the initiation of a phase 1 clinical trial evaluating XL102, both as a single agent and in combination with other anti-cancer therapies for the treatment of inoperable, locally advanced or metastatic solid tumors.
- In February 2021, we announced a collaboration and license agreement with Adagene to utilize Adagene's SAFEbody technology platform to generate masked versions of mAbs from our growing preclinical pipeline for the development of ADCs or other innovative biologics.
- In February 2021, cabozantinib was the subject of multiple data presentations at the virtual American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU 2021), including updated trial results with extended follow-up and patient-reported outcomes from the CheckMate -9ER trial demonstrating continued superior PFS, OS and ORR vs. sunitinib across both the subgroup of 75 patients with sarcomatoid histology and the full study population, as well as significantly improved health-related quality of life. Additional cabozantinib presentations at ASCO GU 2021 included: positive results from PAPMET (also known as SWOG S1500), a randomized phase 2 trial conducted by the Southwest Oncology Group evaluating cabozantinib versus sunitinib in patients with metastatic papillary RCC; positive findings from an international retrospective study of cabozantinib in RCC patients with brain metastases; and positive final results from the phase 1 clinical trial sponsored and conducted by NCI-CTEP, including seven expansion cohorts, evaluating cabozantinib in combination with nivolumab and in combination with both nivolumab and ipilimumab in patients with refractory metastatic genitourinary tumors.
- In February 2021, we announced the FDA had granted Breakthrough Therapy Designation to cabozantinib as a potential treatment for patients with RAI-refractory DTC who have progressed following prior therapy.
- In March 2021, we announced an exclusive license agreement with WuXi Bio for a panel of mAbs, discovered based on WuXi Bio's integrated technology platforms for the development of ADC, bispecific and certain other novel tumor-targeting biologics applications.

- In March 2021, we announced a clinical trial collaboration and supply agreement with Merck KGaA and Pfizer to evaluate the safety and tolerability of XL092 in combination with avelumab in patients with locally advanced or metastatic UC as part of the ongoing STELLAR-001 phase 1b dose escalation study.
- In March 2021, we announced the completion of patient enrollment in COSMIC-313, a phase 3 pivotal trial evaluating the triplet combination of cabozantinib, nivolumab and ipilimumab versus the combination of nivolumab and ipilimumab in patients with previously untreated advanced intermediate- or poor-risk RCC. COSMIC-313 is a multicenter, randomized, double-blind, controlled phase 3 pivotal trial that enrolled approximately 840 patients globally. The primary endpoint of the trial is PFS, and additional endpoints include OS and ORR.
- In March 2021 and April 2021, Ipsen and BMS, respectively, received regulatory approval from the EC for CABOMETYX in combination with OPDIVO as a first-line treatment for patients with advanced RCC.
- In April 2021, we announced the FDA's acceptance of the IND for XB002 and our plans to initiate a phase 1 trial during the second quarter of 2021.
- In May 2021, we announced an asset purchase agreement with GamaMabs to acquire GamaMabs' antibody program directed at AMHR2.
- In May 2021, we received a notice letter from Teva Pharmaceuticals USA, Inc. (Teva) regarding an Abbreviated New Drug Application (ANDA) Teva submitted to the FDA, requesting approval to market a generic version of CABOMETYX tablets. Teva's notice letter included a Paragraph IV certification with respect to our U.S. Patent Nos. 9,724,342 (formulations), 10,034,873 (methods of treatment) and 10,039,757 (methods of treatment), which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book, and expire in 2033, 2031 and 2031, respectively. Teva's notice letter did not provide a Paragraph IV certification against any additional CABOMETYX patents. We are reviewing the details of the Paragraph IV certification notice. We intend to continue to vigorously defend our cabozantinib intellectual property estate.

Financial Highlights

- Net product revenues for the first quarter of 2021 were $227.2 million, compared to $193.9 million for the first quarter of 2020.
- Total revenues for the first quarter of 2021 were $270.2 million, compared to $226.9 million for the first quarter of 2020.
- Research and development expenses for the first quarter of 2021 were $159.3 million, compared to $101.9 million for the first quarter of 2020.
- Selling, general and administrative expenses for the first quarter of 2021 were $102.4 million, compared to $62.9 million for the first quarter of 2020.
- Provision for (benefit from) income taxes for the first quarter of 2021 was $(3.6) million, compared to $11.4 million for the first quarter of 2020.
- Net income for the first quarter of 2021 was $1.6 million, or $0.01 per share, basic and $0.00 per share, diluted, compared to net income of $48.6 million, or $0.16 per share, basic and $0.15 per share diluted, for the first quarter of 2020.
- Cash, cash equivalents, restricted cash equivalents and investments were $1.6 billion as of March 31, 2021, compared to $1.5 billion as of December 31, 2020.

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

Challenges and Risks

In addition to the challenges and risks imposed by the COVID-19 pandemic and described under "—COVID-19 Update" above, we will also continue to face challenges and risks that may impact our ability to execute on our 2021 business objectives, and some of these risks to our business have been or may be exacerbated by the COVID-19 pandemic. In particular, for the foreseeable future, we expect our ability to generate sufficient cash flow to fund our business operations and growth will depend upon the continued commercial success of CABOMETYX, both alone or in combination with other therapies, as a treatment for the highly competitive indications for which it is approved, and possibly for other indications for which cabozantinib has been or is currently being evaluated in potentially label-enabling clinical trials, if warranted by the data generated from these trials. However, we cannot be certain that the clinical trials we and our collaboration partners are currently conducting, or may conduct in the future, will demonstrate adequate safety and efficacy in these additional indications to receive regulatory approval in the major commercial markets where CABOMETYX

is approved. Even if we and our collaboration partners receive the required regulatory approvals to market cabozantinib for additional indications, we and our collaboration partners may not be able to commercialize CABOMETYX effectively and successfully in these additional indications. In addition, CABOMETYX will only continue to be commercially successful if private third-party and government payers continue to provide coverage and reimbursement. However, as is the case for all innovative pharmaceutical therapies, obtaining and maintaining coverage and reimbursement for CABOMETYX is becoming increasingly difficult, both within the U.S. and in foreign markets, because of growing concerns over healthcare cost containment and corresponding policy initiatives and activities aimed at limiting access to, and restricting the prices of, pharmaceuticals.

Achievement of our 2021 business objectives will also depend on our ability to maintain a competitive position with respect to the shifting landscape of therapeutic strategy for the treatment of cancer, which we may not be able to do. While we have had success in adapting our development strategy for the cabozantinib franchise and other product candidates to address the expanding role of therapies that combine targeted agents with ICIs and/or with other mechanisms of action, it is uncertain whether current and future clinical trials will lead to regulatory approvals, or whether physicians will prescribe regimens containing our products instead of competing product combinations. Moreover, the complexities of such a development strategy have required and are likely to continue to require collaboration with some of our competitors. In the longer term, we may eventually face competition from potential manufacturers of generic versions of our marketed products, including the proposed generic versions of CABOMETYX tablets that are the subject of ANDAs submitted to the FDA by MSN Pharmaceuticals, Inc. (MSN) and Teva, and the approval of either MSN's or Teva's ANDA could significantly decrease our revenues derived from the U.S. sales of CABOMETYX and thereby materially harm our business, financial condition and results of operations. Separately, our research and development objectives may be impeded by the challenges of scaling our organization to meet the demands of expanded drug development, unanticipated delays in clinical testing and the inherent risks and uncertainties associated with drug discovery operations, all of which may be increased as a result of the COVID-19 pandemic. In connection with efforts to expand our product pipeline, we may be unsuccessful in discovering new drug candidates or identifying 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 biotechnology, biopharmaceutical and pharmaceutical industries with development and commercial operations. As described under "—COVID-19 Update" above, these risks have been or may be exacerbated by the COVID-19 pandemic. For a more detailed discussion of challenges and risks we face, including those relating to the COVID-19 pandemic, 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 ends on the Friday closest to December 31st. Fiscal year 2021, which is a 52-week fiscal year, will end on December 31, 2021 and fiscal year 2020, which was a 52-week fiscal year, ended on January 1, 2021. For convenience, references in this report as of and for the three months ended April 2, 2021 and April 3, 2020, and as of and for the fiscal year ended January 1, 2021 are indicated as being as of and for the three months ended March 31, 2021 and March 31, 2020, and the year ended December 31, 2020, respectively.

Results of Operations

Revenues

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

	Three Months Ended March 31,		Percent Change
	2021	2020	
Net product revenues	$ 227,212	$ 193,880	17 %
License revenues	27,528	20,879	32 %
Collaboration services revenues	15,490	12,156	27 %
Total revenues	$ 270,230	$ 226,915	19 %

Net Product Revenues

Gross product revenues, discounts and allowances, and net product revenues were as follows (dollars in thousands):

	Three Months Ended March 31,		Percent Change
	2021	2020	
Gross product revenues	$ 314,205	$ 252,566	24 %
Discounts and allowances	(86,993)	(58,686)	48 %
Net product revenues	$ 227,212	$ 193,880	17 %

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

	Three Months Ended March 31,		Percent Change
	2021	2020	
CABOMETYX	$ 223,595	$ 189,216	18 %
COMETRIQ	3,617	4,664	-22 %
Net product revenues	$ 227,212	$ 193,880	17 %

The increase in net product revenues for CABOMETYX for the three months ended March 31, 2021, relative to the corresponding prior year period, was primarily related to an increase in the number of units sold that was partially driven by the strong uptake for the combination therapy of CABOMETYX and OPDIVO following approval by the FDA in January 2021. The decrease in net product revenues for COMETRIQ for the three months ended March 31, 2021, relative to the corresponding prior year period, was due to a decrease in the number of units sold.

We project our net product revenues for the remainder of 2021 may increase relative to the corresponding prior year period, primarily as a result of the growth in the number of units sold following the FDA's approval of CABOMETYX in combination with OPDIVO as a first line treatment of patients with advanced RCC, as well as an increase in selling price.

We recognize product revenues net of discounts and allowances that are described in “Note 1. Organization and Summary of Significant Accounting Policies” to our “Notes to Consolidated Financial Statements” included in our Annual Report on Form 10-K for the year ended December 31, 2020. The increase in discounts and allowances for the three months ended March 31, 2021, relative to the corresponding prior year period, was primarily the result of an increase in Public Health Service hospital utilization and the dollar amount of the related chargebacks, an increase in returns and allowances and an increase in Medicare utilization.

We project our discounts and allowances as a percentage of gross revenues may increase during the remainder of 2021 relative to the corresponding prior year period as the number of patients participating in government programs continues to increase and as the discounts given and rebates paid to government payers also increase.

License Revenues

License revenues include the recognition of the portion of milestone payments allocated to the transfer of intellectual property licenses for which it had become probable in the related period that the milestone would be achieved and a significant reversal of revenues would not occur, as well as royalty revenues and the profit on the U.S. commercialization of COTELLIC from Genentech.

Royalties increased primarily as a result of increases in royalties earned on Ipsen’s net sales of cabozantinib outside of the U.S. and Japan. Ipsen royalties were $22.5 million for the three months ended March 31, 2021, compared to $17.9 million for the comparable period in 2020. Ipsen’s net sales of cabozantinib have continued to grow since their first commercial sale of the product in the fourth quarter of 2016, primarily due to increased demand of CABOMETYX, which, as of March 31, 2021, is approved in 60 countries outside of the U.S. Royalties also increased due to the commercial launch of CABOMETYX for the treatment of patients with curatively unresectable or metastatic RCC in Japan by Takeda during the second quarter of 2020.

Our share of profits on the U.S. commercialization of COTELLIC under our collaboration agreement with Genentech was $1.8 million for the three months ended March 31, 2021, compared to $1.4 million for the corresponding prior year

period. We also earned royalties on ex-U.S. net sales of COTELLIC by Genentech of $1.0 million for the three months ended March 31, 2021, compared to $1.3 million for the corresponding prior year period.

Due to uncertainties surrounding the timing and achievement of regulatory and development milestones, it is difficult to predict future milestone revenues and milestones can vary significantly from period to period. We project our license revenues for the remainder of 2021 to decrease, relative to fiscal 2020, as a result of the anticipated achievement of fewer milestones in 2021, partially offset by an increase in royalty revenues related to an increase in product sales by Ipsen and Takeda.

Collaboration Services Revenues

Collaboration services revenues include the recognition of deferred revenues for the portion of upfront and milestone payments that have been allocated to research and development services performance obligations, development cost reimbursements earned under our collaboration agreements, product supply revenues, net of product supply costs and the royalties we pay on sales by Ipsen and Takeda of products containing cabozantinib. We received notification that, effective January 1, 2021, Royalty Pharma plc acquired from GlaxoSmithKline (GSK) all rights, title and interest in royalties on net product sales containing cabozantinib for non-U.S. markets for the full term of the royalty and for the U.S. market through September 2026, after which time U.S. royalties will revert back to GSK.

Development cost reimbursements were $18.3 million for the three months ended March 31, 2021, compared to $14.4 million for the corresponding prior year period. The increase in development cost reimbursements was primarily a result of the reimbursements from Ipsen and Takeda associated with their decision to opt in and co-fund CONTACT-02 and additional cohorts of COSMIC-021 studies in 2020 and their respective share of the increase in spending on the CONTACT-02 study, partially offset by a decrease in spending on COSMIC-021 and COSMIC-312 studies.

Collaboration services revenues were reduced by $3.3 million for the 3% royalty we are required to pay on the net sales by Ipsen and Takeda of any product incorporating cabozantinib for the three months ended March 31, 2021, compared to $2.4 million for the corresponding prior year period. As royalty generating sales of cabozantinib by Ipsen and Takeda have increased as described above, our royalty payments have also increased.

We project our collaboration services revenues may decrease for the remainder of 2021, relative to fiscal 2020, primarily as a result of lower development cost reimbursements projected to be earned under our collaboration agreements.

Cost of Goods Sold

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

	Three Months Ended March 31,		Percent Change
	2021	2020	
Cost of goods sold	$ 13,198	$ 9,289	42 %
Gross margin	94 %	95 %	

Cost of goods sold is related to our product revenues and consists primarily of a 3% royalty payable on U.S. net sales of any product incorporating cabozantinib, as well as the cost of inventory sold, indirect labor costs, write-downs related to expiring and excess inventory, and other third-party logistics costs. The increase in cost of goods sold for the three months ended March 31, 2021, relative to the corresponding prior year period, was primarily the result of an increase in write-downs for excess and expiring inventory, certain other period costs, as well as an increase in royalties as a result of increased U.S. cabozantinib sales, partially offset by favorable purchase price variances. We do not project our gross margin to change significantly during the remainder of 2021.

Research and Development Expenses

We do not track fully burdened research and development expenses on a project-by-project basis. We group our research and development expenses into three categories: (1) development; (2) drug discovery; and (3) other. Our development group leads the development and implementation of our clinical and regulatory strategies and prioritizes disease indications in which our compounds are being or may be studied in clinical trials. Our drug discovery group utilizes a variety of technologies, including in-licensed technologies, to enable the rapid discovery, optimization and extensive characterization of lead compounds such that we are able to select development candidates with the best potential for further evaluation and advancement into clinical development.

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

	Three Months Ended March 31,		Percent
	2021	2020	Change
Research and development expenses:			
Development:			
Clinical trial costs	$ 60,691	$ 53,344	14 %
Personnel expenses	28,884	20,288	42 %
Consulting and outside services	5,289	3,244	63 %
Other development costs	7,284	4,741	54 %
Total development	102,148	81,617	25 %
Drug discovery:			
License and other collaboration costs	28,438	5,013	467 %
Other drug discovery [1]	11,287	6,734	68 %
Total drug discovery	39,725	11,747	238 %
Other [2]	17,415	8,513	105 %
Total research and development expenses	$ 159,288	$ 101,877	56 %

(1) Primarily includes personnel expenses, consulting and outside services and laboratory supplies.
(2) Includes stock-based compensation, the allocation of general corporate costs to research and development, and development cost reimbursements in connection with our collaboration arrangement with Roche executed in December 2019.

The increase in research and development expenses for the three months ended March 31, 2021, relative to the corresponding prior year period, was primarily related to increases in license and other collaboration costs, clinical trial costs, personnel expenses and stock-based compensation expense. License and other collaboration costs increased primarily due to increases in upfront license fees, program initiation fees and research funding commitments related to business development activities. Clinical trial costs, which include services performed by third-party contract research organizations and other vendors who support our clinical trials, increased primarily due to costs associated with the expanding clinical trial program for cabozantinib. Personnel expenses increased primarily due to increases in headcount to support our expanding discovery and development organization. Stock-based compensation expense increased primarily due to the performance-based restricted stock units (PSUs) granted in 2019 that became probable of achievement during the first quarter of 2021.

In addition to reviewing the three categories of research and development expenses described above, we principally consider qualitative factors in making decisions regarding our research and development programs. These factors include enrollment in clinical trials for our drug candidates, preliminary data and final results from clinical trials, the potential indications for our drug candidates, the clinical and commercial potential for our drug candidates, and competitive dynamics. We also make our research and development decisions in the context of our overall business strategy.

We are focusing our development efforts primarily on cabozantinib to maximize the therapeutic and commercial potential of this compound and, as a result, we project that a significant portion of our research and development expenses will relate to the continuing clinical development program of cabozantinib, which includes over 100 ongoing or planned clinical trials across multiple indications. Notable company-sponsored studies resulting from this program include: COSMIC-021 and COSMIC-312, for which Roche is providing atezolizumab free of charge; COSMIC-313, for which BMS is providing nivolumab and ipilimumab free of charge; CONTACT-02 for which Roche is sharing the development costs and providing atezolizumab free of charge; and COSMIC-311.

We remain committed to expanding our oncology product pipeline through our drug discovery efforts, which encompass both small molecule and biologics programs with multiple modalities and mechanisms of action. In this regard, we conduct drug discovery activities with the goal of identifying new product candidates to advance into clinical trials. In addition, we will continue to engage in business development initiatives aimed at acquiring and in-licensing promising oncology platforms and assets and then further characterize and develop them utilizing our established preclinical and clinical development infrastructure.

We project our research and development expenses may continue to increase for the remainder of 2021 compared to 2020, primarily driven by our ongoing clinical evaluation of cabozantinib, the initiation of new clinical trials and expansion of ongoing clinical trials evaluating other product candidates in our pipeline, including XL092, XL102, and XB002, and anticipated business development activities.

The length of time required for clinical development of a particular product candidate and our development costs for that product candidate may be impacted by the scope and timing of enrollment in clinical trials for the product candidate, our decisions to develop a product candidate for additional indications and whether we pursue development of the product candidate or a particular indication with a collaborator or independently. For example, cabozantinib is being developed in multiple indications, and we do not yet know for how many of those indications we will ultimately pursue regulatory approval. In this regard, our decisions to pursue regulatory approval of cabozantinib for additional indications depend on several variables outside of our control, including the strength of the data generated in our prior, ongoing and potential future clinical trials. Furthermore, the scope and number of clinical trials required to obtain regulatory approval for each pursued indication is subject to the input of the applicable regulatory authorities, and we have not yet sought such input for all potential indications that we may elect to pursue. Even after having given such input, applicable regulatory authorities may subsequently require additional clinical studies prior to granting regulatory approval based on new data generated by us or other companies, or for other reasons outside of our control. As a condition to any regulatory approval, we may also be subject to post-marketing development commitments, including additional clinical trial requirements. As a result of the uncertainties discussed above, we are unable to determine the duration of, or total costs associated with the development of cabozantinib or any of our other research and development projects.

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

Selling, General and Administrative Expenses

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

	Three Months Ended March 31,		Percent Change
	2021	2020	
Selling, general and administrative expenses	$ 102,351	$ 62,940	63 %

Selling, general and administrative expenses consist primarily of personnel expenses, stock-based compensation, marketing costs, and certain other administrative costs.

The increase in selling, general and administrative expenses for the three months ended March 31, 2021, relative to the corresponding prior year period, was primarily related to the increases in personnel expenses, marketing costs, corporate giving and stock-based compensation expense, partially offset by a decrease in the Branded Prescription Drug Fee due to a change in estimate for such fees in 2020 following our receipt of the preliminary fee notice from the Internal Revenue Service. Personnel expenses increased primarily due to increases in administrative headcount to support our commercial and research and development organizations. Marketing costs increased primarily due to increased marketing activities in support of the launch of the combination therapy of CABOMETYX and OPDIVO following approval by the FDA in January 2021. The increase in stock-based compensation expense was primarily due to PSUs granted in 2019 that became probable of achievement during the first quarter of 2021.

We project our selling, general and administrative expenses may continue to increase for the remainder of 2021 relative to 2020 in support of our continued commercial investment in CABOMETYX and the growth in the broader organization.

Non-operating Income

Non-operating income was as follows (dollars in thousands):

	Three Months Ended March 31,		Percent Change
	2021	2020	
Interest income	$ 2,682	$ 7,220	-63 %
Other income (expense), net	(90)	6	n/a
Non-operating income	$ 2,592	$ 7,226	-64 %

The decrease in non-operating income for the three months ended March 31, 2021, relative to the corresponding prior year period, was primarily the result of the decreases in interest income due to lower interest rates.

Provision for (Benefit from) Income Taxes

The provision for (benefit from) income taxes and effective income tax rates were as follows (dollars in thousands):

	Three Months Ended March 31,		Percent Change
	2021	2020	
Provision for (benefit from) income taxes	$ (3,616)	$ 11,423	n/a

We recorded a benefit from income taxes for the three months ended March 31, 2021 as a result of a current period pre-tax loss, relative to the corresponding prior year period in which we reported pre-tax income. The effective tax rate for the three months ended March 31, 2021 differed from the U.S. federal statutory rate of 21% primarily due to excess tax benefits related to the exercise of certain stock options, in relation to the generation of a small pre-tax loss during the period. The effective tax rate for the three months ended March 31, 2020 differed from U.S. federal statutory tax rate of 21% primarily due to excess tax benefits related to the exercise of certain stock options during the period and the generation of federal tax credits.

Liquidity and Capital Resources

As of March 31, 2021, we had $1.6 billion in cash, cash equivalents, restricted cash equivalents and investments, compared to $1.5 billion as of December 31, 2020. We anticipate that the aggregate of our current cash and cash equivalents, short-term investments available for operations, net 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.

We project we may continue to spend significant amounts of cash to fund the continued development and commercialization of cabozantinib. In addition, we intend to continue to expand our oncology product pipeline through our drug discovery efforts, including additional research collaborations, in-licensing arrangements and other business development activities that align with our oncology drug development, regulatory and commercial expertise. Financing these activities could materially impact our liquidity and capital resources and may require us to incur debt or raise additional funds through the issuance of equity. Furthermore, even though we believe we have sufficient funds for our current and future operating plans, we may choose to incur debt or raise additional funds through the issuance of equity due to market conditions or strategic considerations.

Letters of Credit

We have obtained standby letters of credit related to our lease obligations and certain other obligations with combined credit limits of $49.7 million and $1.6 million as of March 31, 2021 and December 31, 2020, respectively. As of March 31, 2021, none of our letters of credit have been drawn upon. All of the letters of credit are fully collateralized by short-term investments.

In January 2021, we entered into a standby letter of credit as guarantee of our obligation to fund our portion of the total tenant improvements related to our build-to-suit lease at our corporate campus. The letter of credit is secured by our short-term investments, which are recorded as restricted cash equivalents and are presented in other long-term assets in

our Condensed Consolidated Balance Sheets and will be reduced as we fund our portion of the tenant improvements. As of March 31, 2021, restricted cash equivalents included $48.2 million of short-term investments as collateral under our standby letter of credit.

Sources and Uses of Cash

Cash flow activities were as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net cash provided by operating activities	$ 39,544	$ 56,074
Net cash provided by investing activities	$ 62,255	$ 32,620
Net cash (used in) provided by financing activities	$ (2,650)	$ 2,145

Operating Activities

Cash flows provided by operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. Cash provided by operating activities is derived by adjusting our net income for: non-cash operating items such as deferred taxes, stock-based compensation, depreciation, non-cash lease expense and changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in our Condensed Consolidated Statements of Income.

Cash provided by operating activities for the three months ended March 31, 2021, decreased relative to the corresponding prior year period, primarily due to an increase in cash paid for operating expenses, which was partially offset by favorable changes in operating assets and liabilities.

Investing Activities

Cash provided by investing activities for the three months ended March 31, 2021 consisted of maturities and sales of investments of $407.4 million, partially offset by cash used in investment purchases of $331.6 million and purchases of property, equipment and other of $13.6 million.

Cash provided by investing activities for the three months ended March 31, 2020 consisted of cash provided by the maturities and sales of investments of $287.1 million, partially offset by cash used in investment purchases of $251.5 million and purchases of property and equipment and other of $3.0 million.

Financing Activities

Cash used in financing activities for the three months ended March 31, 2021 consisted of $5.4 million of withholding taxes paid related to net share settlements of equity awards, partially offset by $2.8 million in proceeds from the issuance of common stock under our equity incentive plans.

Cash provided by financing activities for the three months ended March 31, 2020 consisted of $3.9 million in proceeds from the issuance of common stock under our equity incentive plans, partially offset by $1.8 million of withholding taxes paid related to net share settlements of equity awards.

Contractual Obligations

There were no material changes outside of the ordinary course of business in our contractual obligations as of March 31, 2021 from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

Off-Balance Sheet Arrangements

As of March 31, 2021, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

Critical Accounting Policies and Estimates

The preparation of our Condensed Consolidated Financial Statements conforms to accounting principles generally accepted in the U.S. which requires management to make judgments, estimates and assumptions that affect the reported

amounts of assets, liabilities, equity, revenues and expenses, and related disclosures. An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact our Condensed Consolidated Financial Statements. On an ongoing basis, management evaluates its estimates including, but not limited to: those related to revenue recognition, including determining the nature and timing of satisfaction of performance obligations, and determining the standalone selling price of performance obligations, and variable consideration such as rebates, chargebacks, sales returns and sales allowances as well as milestones included in collaboration arrangements; the amounts of revenues and expenses under our profit and loss sharing agreement; recoverability of inventory; the accrual for certain liabilities including accrued clinical trial liabilities; and valuations of equity awards used to determine stock-based compensation, including certain awards with vesting subject to market or performance conditions; and the amounts of deferred tax assets and liabilities including the related valuation allowance. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results could differ materially from those estimates.

We believe our critical accounting policies relating to revenue recognition, inventory, clinical trial accruals, stock-based compensation and income taxes reflect the most 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, 2021, 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, 2020 submitted to the SEC on February 10, 2021.

Recent Accounting Pronouncements

For a description of the expected impact of recent accounting pronouncements, see “Note 1. Organization and Summary of Significant Accounting Policies” in the “Notes to Condensed Consolidated Financial Statements” contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks as of March 31, 2021 have not changed significantly from those described in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2020.

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

In September 2019, we received a notice letter regarding an ANDA submitted to the FDA by MSN, requesting approval to market a generic version of CABOMETYX tablets. MSN's initial notice letter included a Paragraph IV certification with respect to our U.S. Patent Nos. 8,877,776, 9,724,342, 10,034,873 and 10,039,757, which are listed in the Orange Book. MSN's initial notice letter did not provide a Paragraph IV certification against U.S. Patent No. 7,579,473, the composition of matter patent, or U.S. Patent No. 8,497,284, a method of use patent. On October 29, 2019, we filed a complaint in the United States District Court for the District of Delaware for patent infringement against MSN asserting U.S. Patent No. 8,877,776 arising from MSN's ANDA filing with the FDA. On November 20, 2019, MSN filed its response to the complaint, alleging that U.S. Patent No. 8,877,776 is invalid and not infringed. On May 5, 2020, we received notice from MSN that it had amended its ANDA to assert additional Paragraph IV certifications. The ANDA now requests approval to market a generic version of CABOMETYX tablets prior to expiration of the two previously unasserted CABOMETYX patents: U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284. On May 11, 2020, we filed a complaint in the United States District Court for the District of Delaware for patent infringement against MSN asserting U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284 arising from MSN's amended ANDA filing with the FDA. Neither of our complaints alleges infringement of U.S. Patent Nos. 9,724,342, 10,034,873 and 10,039,757. On May 22, 2020, MSN filed its response to the complaint, alleging that each of U.S. Patent No. 7,579,473 and U.S. Patent No. 8,497,284 is invalid and not infringed. On March 23, 2021, MSN filed its First Amended Answer and Counterclaims (amending its prior filing from May 22, 2020), seeking, among other things, a declaratory judgment that U.S. Patent No. 9,809,549 is invalid and would not be infringed by MSN if its generic version of CABOMETYX tablets were approved by the FDA. On April 7, 2021, we filed our response to MSN's First Amended Answer and Counterclaims, denying, among other things, that U.S. Patent No. 9,809,549 is invalid or would not be infringed. In our complaints, we are seeking, among other relief, an order that the effective date of any FDA approval of the ANDA would be a date no earlier than the expiration of all of U.S. Patent No. 7,579,473, U.S. Patent No. 8,497,284 and U.S. Patent No. 8,877,776, the latest of which expires on October 8, 2030, and equitable relief enjoining MSN from infringing these patents. These lawsuits against MSN have been consolidated, and a bench trial has been scheduled for May 2022.

We may also from time to time become a party or subject to various other legal proceedings and claims, either asserted or unasserted, which arise in the ordinary course of business. Some of these proceedings have involved, and may involve in the future, claims that are subject to substantial uncertainties and unascertainable damages.

Item 1A. Risk Factors

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

Risk Factor Summary

- *Our ability to grow our company is critically dependent upon the commercial success of CABOMETYX in its approved indications and the further clinical development, regulatory approval and commercial success of the cabozantinib franchise in additional indications.*
- *If we are unable to obtain or maintain coverage and reimbursement for our products from third-party payers, our business will suffer.*
- *Pricing for pharmaceutical products in the U.S. has come under increasing attention and scrutiny by federal and state governments, legislative bodies and enforcement agencies. This may result in actions that have the effect of reducing our revenue or harming our business or reputation.*
- *Lengthy regulatory pricing and reimbursement procedures and cost control initiatives imposed by governments outside the U.S. could delay the marketing of and/or result in downward pressure on the price of our approved products, resulting in a decrease in revenue.*
- *Legislation and regulatory action designed to reduce barriers to the development, approval and adoption of generic drugs in the U.S., and the entrance of generic competitors, could limit the revenue we derive from our products, which could have a material adverse impact on our business, financial condition and results of operations.*

- *We are subject to healthcare laws, regulations and enforcement, as well as laws and regulations relating to privacy, data collection and processing of personal data; our failure to comply with those laws could have a material adverse impact on our business, financial condition and results of operations.*
- *Clinical testing of cabozantinib for new indications, or of new product candidates, is a lengthy, costly, complex and uncertain process that may fail ultimately to demonstrate safety and efficacy data for those products sufficiently differentiated to compete in our highly competitive market environment.*
- *The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy and uncertain and may not result in regulatory approvals for additional cabozantinib indications or our other product candidates, which could have a material adverse impact on our business, financial condition and results of operations.*
- *We may be unable to expand our development pipeline, which could limit our growth and revenue potential.*
- *Our profitability could be negatively impacted if expenses associated with our extensive clinical development, business development and commercialization activities, both for the cabozantinib franchise and our earlier-stage product candidates, grow more quickly than the revenues we generate.*
- *Our clinical, regulatory and commercial collaborations with major companies make us reliant on those companies for their continued performance and investments, which subjects us to a number of risks. For example, we rely on Ipsen and Takeda for the commercial success of CABOMETYX in its approved indications outside of the U.S., and are unable to control the amount or timing of resources expended by these collaboration partners in the commercialization of CABOMETYX in its approved indications outside of the U.S. In addition, our growth potential is dependent in part upon companies with which we have entered into research collaborations, in-licensing arrangements and similar business development relationships.*
- *Data breaches, cyber-attacks and other failures in our information technology operations and infrastructure could compromise our intellectual property or other sensitive information, damage our operations and cause significant harm to our business and reputation.*
- *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.*
- *If the COVID-19 pandemic is further prolonged or becomes more severe, our business operations and corresponding financial results could suffer, which could have a material adverse impact on our financial condition and prospects for growth.*
- *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.*

Risks Related to the Commercialization of Our Products

Our ability to grow our company is critically dependent upon the commercial success of CABOMETYX in its approved indications and the further clinical development, regulatory approval and commercial success of the cabozantinib franchise in additional indications.

We anticipate that for the foreseeable future, our ability to maintain or meaningfully increase cash flow to fund our business operations and growth will depend upon the continued commercial success of CABOMETYX, both alone and in combination with other therapies, as a treatment for the highly competitive indications for which it is approved, and possibly for other indications for which cabozantinib has been or is currently being evaluated in potentially label-enabling clinical trials, if warranted by the data generated from these trials. In this regard, part of our strategy is to pursue additional indications for the cabozantinib franchise to increase the number of cancer patients who could benefit from this medicine. However, we cannot be certain that the clinical trials we and our collaboration partners are currently conducting, or may conduct in the future, will demonstrate adequate safety and efficacy in these additional indications to receive regulatory approval in the major commercial markets where CABOMETYX is approved. Even if we and our collaboration partners receive the required regulatory approvals to market cabozantinib for additional indications, we and our collaboration partners may not be able to commercialize CABOMETYX effectively and successfully in these additional indications. If revenue from CABOMETYX decreases or remains flat, or if we are unable to expand the labeled indications in major commercial markets where CABOMETYX is approved, or if we or our collaboration partners fail to achieve anticipated product royalties and collaboration milestones, whether as a result of the COVID-19 pandemic or otherwise, we may need to reduce our operating expenses, access other sources of cash or otherwise modify our business plans, which could have a material adverse impact on our business, financial condition and results of operations.

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

Our ability to increase or maintain revenues from sales of CABOMETYX for its approved indications is, and if approved for additional indications will be, highly dependent upon the extent of market acceptance of CABOMETYX among physicians, patients, government healthcare payers such as Medicare and Medicaid, commercial healthcare plans and the medical community. Market acceptance for CABOMETYX could depend on numerous factors, including the effectiveness and safety profile, or the perceived effectiveness and safety profile, of CABOMETYX compared to competing products, the strength of CABOMETYX sales and marketing efforts and changes in pricing and reimbursement for CABOMETYX. For example, with respect to the FDA approval of CABOMETYX in combination with OPDIVO as a first-line treatment of patients with advanced RCC, we cannot predict whether our commercialization efforts will lead to increased adoption of this combination by healthcare professionals, who may continue to treat first-line RCC patients with competing product combinations and reserve CABOMETYX for later in their treatment plan. If CABOMETYX does not continue to be prescribed broadly for the treatment of its approved RCC and HCC indications, our product revenues could flatten or decrease, which could have a material adverse impact on our business, financial condition and results of operations.

Our competitors may develop products, combination therapies and technologies that impair the relative value of our marketed products and any future product candidates.

The biotechnology, biopharmaceutical and pharmaceutical industries are competitive and are characterized by constant technological change and diverse offerings of products, particularly in the area of novel oncology therapies. Many of our competitors have greater capital resources, larger research and development staff and facilities, deeper regulatory expertise and more extensive product manufacturing and commercial capabilities than we do, which may afford them a competitive advantage. Further, our competitors may be more effective at in-licensing and developing new commercial products that could render our products, and those of our collaboration partners, obsolete and noncompetitive. 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 scientific and clinical research activities similar to ours.

Furthermore, the specific indications for which CABOMETYX is currently or may be approved, based on the results from clinical trials currently evaluating cabozantinib, are highly competitive. Several novel therapies and combinations of therapies have been approved, are in advanced stages of clinical development or are under expedited regulatory review in these indications, and these other therapies are currently competing or are expected to compete with CABOMETYX. Given the shifting landscape of therapeutic strategy following the advent of ICIs, we believe our future success will depend upon our ability to achieve positive clinical trial results for therapies combining cabozantinib with ICIs across multiple indications, and if approved, successfully commercialize such combination therapies. While we have had success in adapting our development strategy for the cabozantinib franchise to address the expanding role of therapies that combine ICIs with other targeted agents, including the FDA approval of CABOMETYX in combination with OPDIVO as a first-line treatment of patients with advanced RCC, it is uncertain whether current and future clinical trials, including those evaluating cabozantinib in combination with an ICI in HCC, NSCLC and mCRPC, will lead to regulatory approvals, or whether physicians will prescribe regimens containing cabozantinib instead of competing product combinations. Moreover, the complexities of such a development strategy have required and are likely to continue to require collaboration with some of our competitors.

If we are unable to maintain or increase our sales, marketing, market access and product distribution capabilities for our products, we may be unable to maximize product revenues, which could have a material adverse impact on our business, financial condition and results of operations.

Maintaining our sales, marketing, market access and product distribution capabilities requires significant resources, and there are numerous risks involved with maintaining and continuously improving such a commercial organization, including our potential inability to successfully recruit, train, retain and incentivize adequate numbers of qualified and effective sales and marketing personnel. We are competing for talent with numerous commercial- and precommercial-stage, oncology-focused biotechnology companies seeking to build out and maintain their commercial organizations, as well as other large pharmaceutical and biotechnology organizations that have extensive, well-funded and more experienced sales and marketing operations, and we may be unable to maintain or adequately scale our commercial organization as a result of such competition. Also, to the extent that the commercial opportunities for CABOMETYX grow over time, we may not properly scale the size and experience of our commercialization teams to market and sell CABOMETYX successfully in an expanded number of indications. If we are unable to maintain or scale our commercial

function appropriately, or should we have to revert back to primarily telephonic and virtual interactions in lieu of in-person meetings with healthcare professionals for an extended period of time as a result of the COVID-19 pandemic, we may not be able to maximize product revenues, which could have a material adverse impact on our business, financial condition and results of operations.

If we are unable to obtain or maintain coverage and reimbursement for our products from third-party payers, our business will suffer.

Our ability to commercialize our products successfully is highly dependent on the extent to which health insurance coverage and reimbursement is, and will be, available from third-party payers, including governmental payers, such as Medicare and Medicaid, and private health insurers. Third-party payers continue to scrutinize and manage access to pharmaceutical products and services and may limit reimbursement for newly approved products and indications. Patients are generally not capable of paying for CABOMETYX or COMETRIQ themselves and rely on third-party payers to pay for, or subsidize, the costs of their medications, among other medical costs. Accordingly, market acceptance of CABOMETYX and COMETRIQ is dependent on the extent to which coverage and reimbursement is available from third-party payers. These entities could refuse, limit or condition coverage for our products, such as by using tiered reimbursement or pressing for new forms of contracting. If third-party payers do not provide coverage or reimbursement for CABOMETYX or COMETRIQ, our revenues and results of operations will suffer. In addition, even if third-party payers provide some coverage or reimbursement for CABOMETYX or COMETRIQ, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans, which often varies based on the type of contract or plan purchased, may not be sufficient for patients to afford CABOMETYX or COMETRIQ.

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

Federal and state governments in the U.S. are considering legislative and regulatory proposals to change the U.S. healthcare system in ways that could affect our ability to continue to commercialize CABOMETYX and COMETRIQ profitably. Similarly, among policy makers and payers, there is significant interest in promoting such changes with the stated goals of containing healthcare costs, improving quality and expanding patient access. The life sciences industry and specifically the market for the sale, insurance coverage and distribution of pharmaceuticals has been a particular focus of these efforts and would likely be significantly affected by any major legislative or regulatory initiatives.

For instance, efforts to repeal, substantially modify or invalidate some or all of the provisions of the Patient Protection and Affordable Care Act of 2010, as amended (PPACA), some of which have been successful, create considerable uncertainties for all businesses involved in healthcare, including our own. Although such efforts have not significantly impacted our business to date, there is no assurance that the repeal, modification or invalidation of some or all of the provisions of the PPACA in the future, will not have a material adverse impact on our business, financial condition and results of operations, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, there are pending federal and state-level legislative proposals that would significantly expand government-provided health insurance coverage, ranging from establishing a single-payer, national health insurance system to more limited “buy-in” options to existing public health insurance programs, each of which could have a significant impact on the healthcare industry. It is also possible that additional governmental actions will be taken in response to the ongoing COVID-19 pandemic, and that such actions would have a significant impact on these public health insurance programs. While we cannot predict how future legislation (or enacted legislation that has yet to be implemented) will affect our business, such proposals could have the potential to impact access to and sales of our products. Furthermore, the expansion of the 340B Drug Discount Program through the PPACA has increased the number of purchasers who are eligible for significant discounts on branded drugs, including our marketed products. Due to general uncertainty in the current regulatory and healthcare policy environment, and specifically regarding positions that the Biden Administration may take with respect to these issues, we are unable to predict the impact of any legislative, regulatory, third-party payer or policy actions, including potential cost containment and healthcare reform measures. If enacted, we and any third parties we may engage may be unable to adapt to any changes implemented as a result of such measures, and we may have difficulties in sustaining profitability or otherwise experience a material adverse impact on our business, financial condition and results of operations.

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

There continue to be U.S. Congressional inquiries, hearings and proposed and enacted federal legislation and rules, as well as executive orders, designed to, among other things: reduce or limit the prices of drugs and make them more affordable for patients (including, for example, by tying the prices that Medicare reimburses for physician-administered drugs to the prices of drugs in other countries); reform the structure and financing of Medicare Part D pharmaceutical benefits, including through increasing manufacturer contributions to offset Medicare beneficiary costs; bring more transparency to drug pricing rationale and methodologies; enable the government to negotiate prices under Medicare; revise rules associated with the calculation of average manufacturer price and best price under Medicaid, which affect the amount of rebates that we pay on prescription drugs under Medicaid and to covered entities under the 340B Drug Discount Program; eliminate the Anti-Kickback Statute (AKS) discount safe harbor protection for manufacturer rebate arrangements with Medicare Part D plan sponsors; create new AKS safe harbors applicable to certain point-of-sale discounts to patients and fixed fee administrative fee payment arrangements with pharmacy benefit managers; and facilitate the importation of certain lower-cost drugs from other countries. While we cannot know the final form or timing of any such legislative, regulatory and/or administrative measures, some of the pending and enacted legislative proposals or executive rulemaking, such as those incorporating International Pricing Index or Most-Favored-Nation models, if implemented without successful legal challenges, would likely have a significant and far-reaching impact on the biopharmaceutical industry and therefore also likely have a material adverse impact on our business, financial condition and results of operations.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing, including the National Medicaid Pooling Initiative. In particular, the obligation to provide notices of price increases to purchasers under laws such as California's SB-17 may influence customer ordering patterns for CABOMETYX and COMETRIQ, which in turn may increase the volatility of our revenues as a reflection of changes in inventory volumes. Furthermore, adoption of these drug pricing transparency regulations, and our associated compliance obligations, may increase our general and administrative costs and/or diminish our revenues. Implementation of these federal and/or state cost-containment measures or other healthcare reforms may limit our ability to generate product revenue or commercialize our products, and in the case of drug pricing transparency regulations, may result in fluctuations in our results of operations.

Lengthy regulatory pricing and reimbursement procedures and cost control initiatives imposed by governments outside the U.S. could delay the marketing of and/or result in downward pressure on the price of our approved products, resulting in a decrease in revenue.

Outside the U.S., including major markets in the EU and Japan, the pricing and reimbursement of prescription pharmaceuticals is generally subject to governmental control. In these countries, pricing and reimbursement negotiations with governmental authorities or payers can take six to 12 months or longer after the initial marketing authorization is granted for a product, or after the marketing authorization for a new indication is granted. This can substantially delay broad availability of the product. To obtain reimbursement and/or pricing approval in some countries, our collaboration partners Ipsen and Takeda may also be required to conduct a study or otherwise provide data that seeks to establish the cost effectiveness of CABOMETYX compared with other available established therapies. The conduct of such a study could also result in delays in the commercialization of CABOMETYX. Additionally, cost-control initiatives, increasingly based on affordability, could decrease the price we and Ipsen might establish for CABOMETYX, or the indications for which we are able to obtain reimbursement, which would result in lower license revenues to us.

Legislation and regulatory action designed to reduce barriers to the development, approval and adoption of generic drugs in the U.S., and the entrance of generic competitors, could limit the revenue we derive from our products, which could have a material adverse impact on our business, financial condition and results of operations.

Under the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA can approve an ANDA for a generic version of a branded drug without the applicant undertaking the human clinical testing necessary to obtain approval to market a new drug. The FDA can also approve a New Drug Application (NDA) under section 505(b)(2) of the FDCA that relies in part on the agency's findings of safety and/or effectiveness for a previously approved drug, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. Both the ANDA and 505(b)(2) NDA processes are discussed in more detail in "Item 1.

Business—Government Regulation—FDA Review and Approval" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 submitted to the SEC on February 10, 2021. In either case, if an ANDA or 505(b)(2) NDA applicant submits an application referencing one of our marketed products prior to the expiry of one or more our Orange Book-listed patents for the applicable product, we may litigate with the potential generic competitor to protect our patent rights, which would result in substantial costs, divert the attention of management, and could have an adverse impact on our stock price. For example, MSN and Teva have separately submitted ANDAs to the FDA requesting approval to market their respective generic versions of CABOMETYX tablets. For a more detailed discussion of the litigation matter involving MSN, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q. It is possible that MSN, Teva or other companies, following FDA approval of an ANDA or 505(b)(2) NDA, could introduce generic or otherwise competitor versions of our marketed products before our patents expire if they do not infringe our patents or if it is determined that our patents are invalid or unenforceable, and we expect that generic cabozantinib products would be offered at a significantly lower price compared to our marketed cabozantinib products. Therefore, regardless of the regulatory approach, the introduction of a generic version of cabozantinib could significantly decrease our revenues derived from the U.S. sales of CABOMETYX and thereby materially harm our business, financial condition and results of operations.

The U.S. federal government has also taken numerous legislative and regulatory actions to expedite the development and approval of generic drugs and biosimilars. The FDA Reauthorization Act of 2017 includes, inter alia, measures to expedite the development and approval of generic products, where generic competition is lacking even in the absence of exclusivities or listed patents. In addition, the FDA has also released a Drug Competition Action Plan, which proposes actions to broaden access to generic drugs and lower consumers' healthcare costs by, among other things, improving the efficiency of the generic drug approval process and supporting the development of complex generic drugs, and the FDA has taken and continues to take steps to implement this plan. Moreover, both Congress and the FDA are considering various legislative and regulatory proposals focused on drug competition, including legislation focused on drug patenting and provision of drug to generic applicants for testing. For example, the Further Consolidated Appropriations Act, 2020, which incorporated the framework from the Creating and Restoring Equal Access To Equivalent Samples (CREATES) legislation, was signed into law as part of the 2019 year-end federal spending package. The legislation purports to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, including by allowing ANDA, 505(b)(2) NDA or biosimilar developers to obtain access to branded drug and biological product samples. While the full impact of these provisions is unclear at this time, its provisions do have the potential to facilitate the development and future approval of generic versions of our products, introducing generic competition that could have a material adverse impact on our business, financial condition and results of operations.

Risks Related to Healthcare Regulatory and Other Legal Compliance Matters

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

We are subject to federal and state healthcare laws and regulations, which laws and regulations are enforced by the federal government and the states in which we conduct our business. Should our compliance controls prove ineffective at preventing or mitigating the risk and impact of improper business conduct or inaccurate reporting, we could be subject to enforcement of the following, including, without limitation:

- the federal AKS;
- the FDCA and its implementing regulations;
- federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations, as amended;
- state law equivalents of each of the above federal laws;
- the Open Payments program of the PPACA;
- state and local laws and regulations that require drug manufacturers to file reports relating to marketing activities, payments and other remuneration and items of value provided to healthcare professionals and entities; and
- state and federal pharmaceutical price and price reporting laws and regulations.

In addition, we may be subject to the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, medical professionals employed by national healthcare programs) and its foreign equivalents, as well as federal and state consumer protection and unfair competition laws.

These federal and state healthcare laws and regulations govern drug marketing practices, including off-label promotion. If our operations are found, or even alleged, to be in violation of the laws described above or other governmental regulations that apply to us, we, or our officers or employees, may be subject to significant 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, imprisonment, reputational harm, additional reporting requirements and oversight, any of which would adversely affect our ability to sell our products and operate our business and also adversely affect our financial results. Furthermore, responding to any such allegation and/or defending against any such enforcement actions can be time-consuming and would require significant financial and personnel resources. Therefore, if any state or the federal government initiates an enforcement action against us, our business may be impaired, and even if we are ultimately successful in our defense, litigating these actions could result in substantial costs and divert the attention of management.

Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer patient assistance programs and donations to patient assistance foundations created by charitable organizations could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

To help patients afford our products, we have a patient assistance program and also occasionally make donations to independent charitable foundations that help financially needy patients. These types of programs designed to assist patients with affording pharmaceuticals have become the subject of Congressional interest and enhanced government scrutiny. The U.S. Department of Health and Human Services Office of Inspector General established guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations that provide co-pay assistance to Medicare patients, provided that manufacturers meet certain specified compliance requirements. In the event we make such donations but are found not to have complied with these guidelines and other laws or regulations respecting the operation of these programs, we could be subject to significant damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. We also rely on a third-party hub provider and exercise oversight to monitor patient assistance program activities. Hub providers are generally hired by manufacturers to assist patients with insurance coverage, financial assistance and treatment support after the patients receive a prescription from their healthcare professional. For manufacturers of specialty pharmaceuticals (including our marketed products), the ability to have a single point of contact for their therapies helps ensure efficient medication distribution to patients. Accordingly, our hub activities are also subject to scrutiny and may create risk for us if not conducted appropriately. A variety of entities, including independent charitable foundations and pharmaceutical manufacturers, but not including our company, have received subpoenas from the U.S. Department of Justice and other enforcement authorities seeking information related to their patient assistance programs and support. Should we or our hub providers receive a subpoena or other process, regardless of whether we are ultimately found to have complied with the regulations governing patient assistance programs, this type of government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

We are subject to laws and regulations relating to privacy, data protection and the collection and processing of personal data. Failure to maintain compliance with these regulations could create additional liabilities for us.

The legislative and regulatory landscape for privacy and data protection continues to evolve globally and in the U.S. For example, the California Consumer Privacy Act of 2018 (CCPA) went into operation in 2020 and affords California residents expanded privacy rights and protections, including civil penalties for violations and statutory damages under a private right of action for data security breaches. These protections will be expanded by California Privacy Rights Act of 2020 (CPRA), which will be operational in most key respects on January 1, 2023. Similar legislative proposals are being advanced in other states and Congress is also considering federal privacy legislation. In addition, most healthcare providers are subject to privacy and security requirements under HIPAA. Although we are not considered to be a covered entity or business associate under HIPAA, we could be subject to penalties if we use or disclose individually identifiable health information in a manner not authorized or permitted by HIPAA. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. For example, the EU General Data Protection Regulation 2016/679 (GDPR) regulates the processing of personal data of individuals within the EU, even if, under certain circumstances, that processing occurs outside the EU, and also places restrictions on transfers of such data to countries

outside of the EU, including the U.S. Should we fail to provide adequate privacy or data security protections or maintain compliance with these laws and regulations, including the CCPA, CPRA and GDPR, we could be subject to sanctions or other penalties, litigation or an increase in our cost of doing business.

Risks Related to Growth of Our Product Portfolio and Research and Development

Clinical testing of cabozantinib for new indications, or of new product candidates, is a lengthy, costly, complex and uncertain process that may fail ultimately to demonstrate safety and efficacy data for those products sufficiently differentiated to compete in our highly competitive market environment.

Clinical trials are inherently risky and may reveal that cabozantinib, despite its approval for certain indications, or a new product candidate, is ineffective or has an unacceptable safety profile with respect to an intended use. Such results may significantly decrease the likelihood of regulatory approval of that product for a particular indication. Moreover, the results of preliminary studies do not necessarily predict clinical or commercial success, and late-stage or other potentially label-enabling clinical trials may fail to confirm the results observed in early-stage trials or preliminary studies. Although we have established timelines for manufacturing and clinical development of cabozantinib and our other product candidates based on existing knowledge of our compounds in development and industry metrics, we may not be able to meet those timelines.

We may experience numerous unforeseen events, during or as a result of clinical investigations, that could delay or prevent commercialization of cabozantinib (or of other product candidates) in new indications, and in some cases, as described in the risk factor titled, "*If the COVID-19 pandemic is further prolonged or becomes more severe, our business operations and corresponding financial results could suffer, which could have a material adverse impact on our financial condition and prospects for growth,*" the COVID-19 pandemic has already increased and may further increase the potential for such developments to occur. These may include:

- lack of acceptable efficacy or a tolerable safety profile;
- negative or inconclusive clinical trial results that require us to conduct further testing or to abandon projects;
- discovery or commercialization by our competitors of other compounds or therapies that show significantly improved safety or efficacy compared to cabozantinib or our other product candidates;
- our inability to identify and maintain a sufficient number of trial sites;
- lower-than-anticipated patient registration or enrollment in our clinical testing;
- additional complexities posed by clinical trials evaluating cabozantinib or our other product candidates in combination with other therapies, including the failure by our collaboration partners to provide us with an adequate and timely supply of product that complies with the applicable quality and regulatory requirements for a combination trial;
- failure of our third-party contract research organizations or investigators to satisfy their contractual obligations, including deviating from any trial protocols; and
- withholding of authorization from regulators or institutional review boards to commence or conduct clinical trials or delays, suspensions or terminations of clinical research for various reasons, including noncompliance with regulatory requirements or a determination by these regulators and institutional review boards that participating patients are being exposed to unacceptable health risks.

If there are further delays in or termination of the clinical testing of cabozantinib or our other product candidates due to any of the events described above or otherwise, our expenses could increase and our ability to generate revenues could be impaired, either of which could adversely impact our financial results. Furthermore, we rely on our collaboration partners to fund a significant portion of our clinical development programs. Should one or all of our collaboration partners decline to support future planned clinical trials, we will be entirely responsible for financing the further development of the cabozantinib franchise or our other product candidates and, as a result, we may be unable to execute our current business plans, which could have a material adverse impact on our business, financial condition and results of operations.

We may not be able to pursue the further development of the cabozantinib franchise or our other product candidates or meet current or future requirements of the FDA or regulatory authorities in other jurisdictions in accordance with our stated timelines or at all. Our planned clinical trials may not begin on time, or at all, may not be completed on schedule, or at all, may not be sufficient for registration of our product candidates or may not result in an approvable product. The duration and the cost of clinical trials vary significantly as a result of factors relating to the clinical trial, including, among others: characteristics of the product candidate under investigation; the number of patients who

ultimately participate in the clinical trial; the duration of patient follow-up; the number of clinical sites included in the trials; and the length of time required to enroll eligible patients.

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 additional cabozantinib indications or our other product candidates, which could have a material adverse impact on our business, financial condition and results of operations.

The activities associated with the research, development and commercialization of the cabozantinib franchise and our other product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the U.S., as well as by comparable authorities in other territories. The processes 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 they 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 EMA or any application or submission to regulatory authorities in other jurisdictions, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

Any clinical trial may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or sNDA or decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, we may encounter delays or rejections based upon changes in policy, which could cause delays in the approval or rejection of an application for cabozantinib or for our other product candidates.

Even if the FDA or a comparable authority in another jurisdiction approves cabozantinib for one or more new indications, such approval may be limited, imposing significant restrictions on the indicated uses, conditions for use, labeling, distribution, and/or production of the product and could impose requirements for post-approval studies, including additional research and clinical trials, all of which may result in significant expense and limit our and our collaboration partners' ability to commercialize cabozantinib in one or more new indications. For example, based on the regulatory feedback from the FDA, and if supported by the clinical data from COSMIC-021, we intend to submit an sNDA to the FDA seeking accelerated approval of cabozantinib in an mCRPC indication in 2021. We expect that as a condition of any potential accelerated approval, the FDA will require us to perform confirmatory post-marketing clinical trials to confirm the clinical benefit, if any, of cabozantinib in combination with Roche's atezolizumab in patients with locally advanced or metastatic solid tumors, such as mCRPC. Failure to complete post-marketing requirements of the FDA in connection with a specific approval in accordance with the timelines and conditions set forth by the FDA could significantly increase costs or delay, limit or ultimately restrict the commercialization of cabozantinib in that indication. Regulatory agencies could also impose various administrative, civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval. Further, current or any future laws or executive orders enacted or executed in response to the COVID-19 pandemic could have a material adverse impact on our business, financial condition, and results of operations.

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

Our business is focused on the discovery, development and commercialization of new medicines for difficult-to-treat cancers. In this regard, we have invested in substantial technical, financial and human resources toward drug discovery activities with the goal of identifying new product candidates to advance into clinical trials. Notwithstanding this investment, many programs that initially show promise will ultimately fail to yield product candidates for multiple reasons. For example, product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profiles or other characteristics suggesting that they are unlikely to be commercially viable products.

Apart from our drug 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 and technologies. However, the in-licensing and acquisition of product candidates and technologies is a highly competitive area, and many other companies are pursuing the same or similar product candidates and technologies to those that we may consider attractive. In particular, larger companies with more capital resources and more extensive clinical development and commercialization

capabilities may have a competitive advantage over us. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may also be unable to in-license or acquire additional product candidates and technologies on acceptable terms that would allow us to realize an appropriate return on our investment. Even if we succeed in our efforts to obtain rights to suitable product candidates and technologies, the competitive business environment may result in higher acquisition or licensing costs, and our investment in these potential products and technologies will remain subject to the inherent risks associated with the development and commercialization of new medicines. In certain circumstances, we may also be reliant on the licensor for the continued development of the in-licensed technology and their efforts to safeguard their underlying intellectual property.

With respect to acquisitions, we may not be able to integrate the target company successfully into our existing business, maintain the key business relationships of the target company, or retain key personnel of the acquired business. Furthermore, we could assume unknown or contingent liabilities or otherwise 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 financial condition and results of operations. If our drug discovery efforts, including research collaborations, in-licensing arrangements and other business development activities, do not result in suitable product candidates, our business and prospects for growth could suffer.

Risks Related to Financial Matters and Capital Requirements

Our profitability could be negatively impacted if expenses associated with our extensive clinical development, business development and commercialization activities, both for the cabozantinib franchise and our earlier-stage product candidates, grow more quickly than the revenues we generate.

Although we reported net income of $1.6 million for the three months ended March 31, 2021 and $111.8 million for the year ended December 31, 2020, we may not be able to maintain or increase profitability on a quarterly or annual basis, and we are unable to predict the extent of future profits or losses. The amount of our net profits or losses will depend, in part, on: the level of sales of CABOMETYX and COMETRIQ in the U.S.; our achievement of clinical, regulatory and commercial milestones, if any, under our collaboration agreements; the amount of royalties from sales of CABOMETYX and COMETRIQ outside of the U.S. under our collaboration agreements; other collaboration revenues; and the level of our expenses, including those associated with our extensive drug discovery, clinical development, business development and commercialization activities, both for the cabozantinib franchise and our earlier-stage product candidates. For example, we reported a net loss for the quarter ended September 30, 2020, primarily due to substantial increases in clinical trial costs, license and other collaboration costs, and personnel expenses relative to the prior fiscal quarters, and it is possible that we may experience net losses in future fiscal quarters or fiscal years, whether due to increases in costs and expenses or otherwise. We expect to continue to spend substantial amounts to fund the continued development of the cabozantinib franchise for additional indications and the commercialization of our approved products. In addition, we intend to continue to expand our oncology product pipeline through our drug discovery efforts, including research collaborations, in-licensing arrangements and other business development activities that align with our oncology drug development, regulatory and commercial expertise, which efforts could involve substantial costs. To offset these costs in the future, we will need to generate substantial revenues. If these costs exceed our current expectations, or we fail to achieve anticipated revenue targets, the market value of our common stock may decline.

If additional capital is not available to us when we need it, we may be unable to expand our product offerings and maintain business growth.

Our commitment of cash resources to CABOMETYX and the reinvestment in our product pipeline through the continued development of the cabozantinib franchise and increasing drug discovery activities, as well as through the execution of business development transactions, could require us to obtain additional capital. We may seek such additional capital through some or all of the following methods: corporate collaborations; licensing arrangements; and public or private debt or equity financings. Our ability to obtain additional capital may depend on prevailing economic conditions and financial, business and other factors beyond our control. Disruptions in the U.S. and global financial markets, including disruptions that have resulted and may continue to result from the COVID-19 pandemic and the related downturn in the U.S. and global economy, as well as future potential U.S. federal government shutdowns, rising interest rate environments, increased or changed tariffs and trade restrictions or otherwise, may adversely impact the availability and cost of credit, as well as our ability to raise additional funds in the capital markets. Economic and capital markets conditions have been, and continue to be, volatile. Continued instability in these market conditions may limit our ability to access the capital necessary

to fund and grow our business. In particular, our inability to access additional funds, whether due to the COVID-19 pandemic or otherwise, could in the future inhibit our ability to engage in larger-scale strategic transactions or investments. We do not know whether additional capital will be available when needed, or that, if available, we will obtain additional capital on terms favorable to us or our stockholders. If we are unable to raise additional funds when we need them, we may be unable to expand our product offerings and maintain business growth, which could have a material adverse impact on our business, financial condition and results of operations.

Risks Related to Our Relationships with Third Parties

We rely on Ipsen and Takeda for the commercial success of CABOMETYX in its approved indications outside of the U.S., and are unable to control the amount or timing of resources expended by these collaboration partners in the commercialization of CABOMETYX in its approved indications outside of the U.S.

We rely upon the regulatory, commercial, medical affairs, market access and other expertise and resources of our collaboration partners, Ipsen and Takeda, for commercialization of CABOMETYX in their respective territories outside of the U.S. We cannot control the amount and timing of resources that our collaboration partners dedicate to the commercialization of CABOMETYX, or to its marketing and distribution, and our ability to generate revenues from the commercialization of CABOMETYX by our collaboration partners depends on their ability to obtain and maintain regulatory approvals for, achieve market acceptance of, and to otherwise effectively market, CABOMETYX in its approved indications in their respective territories. Further, the operations of our collaboration partners, and ultimately their sales of CABOMETYX in their respective territories outside of the U.S., could be adversely affected by the degree and effectiveness of their respective corporate responses to the COVID-19 pandemic, as well as by the imposition of governmental price or other controls, political and economic instability, trade restrictions or barriers and changes in tariffs, escalating global trade and political tensions, or other factors. If our collaboration partners are unable or unwilling to invest the resources necessary to commercialize CABOMETYX successfully in the EU, Japan and other international territories where it has been approved, this could reduce the amount of revenue we are due to receive under these collaboration agreements, thus resulting in harm to our business and operations.

Our clinical, regulatory and commercial collaborations with major companies make us reliant on those companies for their continued performance and investments, which subjects us to a number of risks.

We have established clinical and commercial collaborations with leading biotechnology, biopharmaceutical and pharmaceutical companies, including, Ipsen, Takeda, Roche and Genentech, BMS, Merck KGgA, Pfizer and Daiichi Sankyo, for the development and commercialization of our products, and our dependence on these collaboration partners subjects us to a number of risks, including, but not limited to:

- our collaboration partners' decision to terminate our collaboration, or their failure to comply with the terms of our collaboration agreements and related ancillary agreements, either intentionally or as a result of negligent performance;
- our inability to control the amount and timing of resources that our collaboration partners devote to the development or commercialization of our products;
- the possibility that our collaboration partners may stop or delay clinical trials, fail to supply us on a timely basis with product required for a combination trial (including as a result of the COVID-19 pandemic), or deliver product that fails to meet appropriate quality and regulatory standards;
- disputes that may arise between us and our collaboration partners that result in the delay or termination of the 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;
- the possibility that our collaboration partners may experience financial difficulties, including, without limitation, difficulties arising from the impact of the COVID-19 pandemic that prevent them from fulfilling their obligations under our agreements;
- our collaboration partners' inability to obtain regulatory approvals in a timely manner, or at all;
- our collaboration partners' failure to comply with legal and regulatory requirements relevant to the authorization, marketing, distribution and supply of our marketed products in the territories outside the U.S. where they are approved; and
- our collaboration partners' failure to properly maintain or defend our intellectual property rights or their use of our intellectual property rights or proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation.

If any of these risks materialize, we may not receive collaboration revenues or otherwise realize anticipated benefits from such collaborations, and our product development efforts and prospects for growth could be delayed or disrupted, all of which could have a material adverse impact on our business, financial condition and results of operations.

Our growth potential is dependent in part upon companies with which we have entered into research collaborations, in-licensing arrangements and similar business development relationships.

To expand our early-stage product pipeline, we have augmented our drug discovery activities with multiple research collaborations and in-licensing arrangements with other companies. Our dependence on our relationships with these research and in-licensing partners subjects us to numerous risks, including, but not limited to:

- our research and in-licensing partners' decision to terminate our relationship, or their failure to comply with the terms of our agreements, either intentionally or as a result of negligent performance;
- disputes that may arise between us and our research and in-licensing partners that result in the delay or termination of research activities with respect to any in-licensed assets or supporting technology platforms;
- the possibility that our research and in-licensing partners may experience financial difficulties, including, without limitation, difficulties arising from the impact of the COVID-19 pandemic, which prevent them from fulfilling their obligations under our agreements;
- our research and in-licensing partners' failure to properly maintain or defend their intellectual property rights or their use of third-party intellectual property rights or proprietary information in such a way as to invite litigation that could jeopardize or invalidate our license to develop these assets or utilize technology platforms
- laws, regulations or practices imposed by countries outside the U.S. that could impact or inhibit scientific research or the development of healthcare products by foreign competitors or disadvantage healthcare products made by foreign competitors, or general political or economic instability in those countries, any of which could complicate, interfere with or impede our relationships with our ex-U.S. research, development and in-licensing partners; and
- our research and in-licensing partners' failure to comply with applicable healthcare laws, as well as established guidelines, laws and regulations related to Good Manufacturing Practice and Good Laboratory Practice.

If any of these risks materialize, we may not be able to expand our product pipeline or otherwise realize a return on the resources we will have invested to develop these early-stage assets, which could have a material adverse impact on our financial condition and prospects for growth.

If third parties upon which we rely to perform clinical trials for cabozantinib in new indications or for new product candidates do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize cabozantinib or other product candidates beyond currently approved indications.

We do not have the ability to conduct clinical trials for cabozantinib or for new potential product candidates independently, 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, whether as a result of the COVID-19 pandemic or otherwise, or if the third parties must be replaced or if the quality or accuracy of the data they generate or provide is compromised due to their failure to adhere to our clinical trial or data security protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or commercialize cabozantinib or other product candidates beyond currently approved indications. In addition, due to the complexity of our research initiatives, we may be unable to engage with third-party contract research organizations that have the necessary experience and sophistication to help advance our drug discovery efforts, which would impede our ability to identify, develop and commercialize our potential product candidates.

We lack our own manufacturing and distribution capabilities necessary for us to produce materials required for certain preclinical activities and to produce and distribute our products for clinical development or for commercial sale, and our reliance on third parties for these services subjects us to various risks.

We do not own or operate manufacturing facilities, distribution facilities or resources for chemistry, manufacturing and control development activities, preclinical, clinical or commercial production and distribution for our current products and new product candidates. Instead, we rely on various third-party contract manufacturing organizations to conduct these operations on our behalf. As our operations continue to grow in these areas, we continue to expand our supply chain

through secondary third-party contract manufacturers, distributors and suppliers. To establish and manage our supply chain requires a significant financial commitment, the creation of numerous third-party contractual relationships and continued oversight of these third parties to fulfill compliance with applicable regulatory requirements. Although we maintain significant resources to directly and effectively oversee the activities and relationships with the companies in our supply chain, we do not have direct control over their operations.

Our third-party contract manufacturers may not be able to produce material on a timely basis or manufacture material with the required quality standards, or in the quantity required to meet our preclinical, clinical development and commercial needs and applicable regulatory requirements, including as a result of the COVID-19 pandemic. Although we have not yet experienced production delays or seen significant impairment to our supply chain as a result of the COVID-19 pandemic, our third-party contract manufacturers, distributors and suppliers could experience operational delays due to facility closures and other hardships as a result of the COVID-19 pandemic, which could impact our supply chain by potentially causing delays to or disruptions in the supply of our commercial or clinical products or product candidates. If our third-party contract manufacturers, distributors and suppliers do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or if they otherwise fail or refuse to comply with their obligations to us under our manufacturing, distribution and supply arrangements, we may not have adequate remedies for any breach. Furthermore, their failure to supply us could impair or preclude meeting commercial or clinical product supply requirements for us or our partners, which could delay product development and future commercialization efforts and have a material adverse impact on our business, financial condition and results of operations. In addition, through our third-party contract manufacturers and data service providers, we continue to provide serialized commercial products as required to comply with the Drug Supply Chain Security Act (DSCSA). If our third-party contract manufacturers or data service providers fail to support our efforts to continue to comply with DSCSA and any future federal or state electronic pedigree requirements, we may face legal penalties or be restricted from selling our products.

If third-party scientific advisors and contractors we rely on to assist with our drug discovery efforts do not perform as expected, the expansion of our product pipeline may be delayed.

We work with scientific advisors at academic and other institutions, as well as third-party contractors in various locations throughout the world, that assist us in our research and development efforts, including in drug discovery and preclinical development strategy. These third parties are not our employees and may have other commitments or contractual obligations that limit their availability to us. Although these third-party scientific advisors and contractors generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. There has also been increased scrutiny surrounding the disclosures of payments made to medical researchers from companies in the pharmaceutical industry, and it is possible that the academic and other institutions that employ these medical researchers may prevent us from engaging them as scientific advisors and contractors or otherwise limit our access to these experts, or that the scientific advisors themselves may now be more reluctant to work with industry partners. Even if these scientific advisors and contractors with whom we have engaged intend to meet their contractual obligations, their ability to perform services may be impacted by external factors, as we experienced in the early stages of the COVID-19 pandemic. If we experience additional delays in the receipt of services, lose work performed by these scientific advisors and contractors or are unable to engage them in the first place, our discovery and development efforts with respect to the matters on which they were working or would work in the future may be significantly delayed or otherwise adversely affected.

Risks Related to Our Information Technology and Intellectual Property

Data breaches, cyber-attacks and other failures in our information technology operations and infrastructure could compromise our intellectual property or other sensitive information, damage our operations and cause significant harm to our business and reputation.

In the ordinary course of our business, we and our third-party service providers, such as contract research organizations, 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 collaboration partners. We have also outsourced significant elements of our information technology infrastructure to third parties and, as a result, such third parties may or could have access to our confidential information. The secure maintenance of this information is critical to our business and reputation, and while we have enhanced and are continuing to enhance our cybersecurity efforts commensurate with the growth and complexity of our business, our systems and those of third-party service providers may be vulnerable to a

cyber-attack. The level of vulnerabilities that exist under normal conditions may have been exacerbated by the fact that, during the COVID-19 pandemic, the portion of our workforce operating remotely has increased, at least temporarily, and some phishing attacks are specifically designed to target remote workers. In addition, we are heavily dependent on the functioning of our information technology infrastructure to carry out our business processes, such as external and internal communications or access to clinical data and other key business information. Accordingly, both inadvertent disruptions to this infrastructure and cyber-attacks could cause us to incur significant remediation or litigation costs, result in product development delays, disrupt critical business operations, expend key information technology resources and divert the attention of management.

Although the aggregate impact of cyber-attacks on our operations and financial condition has not been material to date, we and our third-party service providers have frequently been the target of threats of this nature and expect them to continue. Any data breach and/or unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose our sensitive business information or sensitive business information of our collaboration partners, which may lead to significant liability for us. A data security breach could also lead to public exposure of personal information of our clinical trial patients, employees or others and result in harm to our reputation and business, compel us to comply with federal and/or state breach notification laws and foreign law equivalents including the GDPR, subject us to investigations and mandatory corrective action, or otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant financial exposure. Furthermore, the costs of maintaining or upgrading our cybersecurity systems (including the recruitment and retention of experienced information technology professionals, who are in high demand) at the level necessary to keep up with our expanding operations and prevent against potential attacks are increasing, and despite our best efforts, our network security and data recovery measures and those of our third-party service providers may still not be adequate to protect against such security breaches and disruptions, which could cause material harm to our business, financial condition and results of operations.

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

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biopharmaceutical companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as, where and when we deem lawful and appropriate. However, these applications may be challenged or may fail to result in issued patents. Our issued patents have been and may in the future be challenged by third parties as invalid or unenforceable under U.S. or foreign laws, or they may be infringed by third parties, and we are from time to time involved in the defense and enforcement of our patents or other intellectual property rights in a court of law, U.S. Patent and Trademark Office *inter partes* review or reexamination proceeding, foreign opposition proceeding or related legal and administrative proceeding in the U.S. and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our intellectual property without a license and/or allow third parties to introduce generic and other competing products, any of which would negatively impact our business. Third parties may also attempt to invalidate or design around our patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of cabozantinib. For example, we received Paragraph IV certification notice letters from MSN and Teva concerning the respective ANDAs that each had filed with the FDA seeking approval to market their respective generic versions of CABOMETYX tablets. Should MSN, Teva or any other third parties receive FDA approval of an ANDA or a 505(b)(2) NDA with respect to cabozantinib, it is possible that such company or companies could introduce generic versions of our marketed products before our patents expire if they do not infringe our patents or if it is determined that our patents are invalid or unenforceable, and the resulting generic competition could have a material adverse impact on our business, financial condition and results of operations.

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

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

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

Our commercial success depends in part upon our ability to avoid infringing patents and proprietary rights of third parties and not to breach any licenses that we have entered into with regard to our technologies and the technologies of third parties. Other parties have filed, and in the future are likely to file, patent applications covering products and technologies that we have developed or intend to develop. If patents covering technologies required by our operations are issued to others, we may have to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, and may require us to pay substantial royalties, grant a cross-license to some of our patents to another patent holder or redesign the formulation of a product candidate so that we do not infringe third-party patents, which may be impossible to accomplish or could require substantial time and expense. In addition, we may be subject to claims that our employees or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that they used or sought to use patent inventions belonging to their former employers. Furthermore, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on their patents or otherwise employs their proprietary technology without authorization. Regardless of their merit, such claims could require us to incur substantial costs and divert the attention of management and key technical personnel in defending ourselves against any such claims or enforcing our own patents. In the event of any third party's successful claim of patent infringement or misappropriation of trade secrets, we may lose valuable intellectual property rights or personnel, which could impede or prevent the achievement of our product development goals, or we may be required to pay damages and obtain one or more licenses from these third parties, subjecting us to substantial royalty payment obligations. We may not be able to obtain these licenses on commercially reasonable terms, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize products.

Risks Related to Our Operations, Managing Our Growth and Employee Matters

If the COVID-19 pandemic is further prolonged or becomes more severe, our business operations and corresponding financial results could suffer, which could have a material adverse impact on our financial condition and prospects for growth.

To date, the COVID-19 pandemic has had a modest impact on our business operations, in particular on our clinical trial, drug discovery and commercial activities. For example, to varying degrees and at different rates across our clinical trials, we experienced declines in screening and enrollment activity during the early days of the COVID-19 pandemic, as well as delays in new site activations and restrictions on access to treatment sites that is necessary to monitor clinical study progress and initiation. However, as the COVID-19 pandemic continues to surge or continues to have a significant presence in various parts of the world, the impact on our clinical development operations could continue or grow more severe. We anticipate that a further prolonged, or more severe, global public health crisis could limit our ability to identify and work with clinical investigators at clinical trial sites globally to enroll, initiate and maintain treatment per protocol of patients for our ongoing clinical trials. Disruptions to medical and administrative operations at clinical trial sites and the implementation

of crisis management initiatives have and may continue to reduce personnel and other resources necessary to conduct our clinical trials, which could delay our clinical trial plans or require certain trials to be temporarily suspended. Moreover, quarantines and travel restrictions have impeded and may continue to impede patient movement or interrupt healthcare services, which we anticipate over time, could also interfere with and potentially negatively impact clinical trial execution, and ultimately results. In addition, increased costs connected with our efforts to mitigate the adverse impacts resulting from the COVID-19 pandemic on our clinical trials could cause the expenses we incur in conducting those clinical trials to increase considerably. Specifically, with respect to our clinical trials evaluating cabozantinib in combination with therapies that must be administered via professional intravenous infusion, such as COSMIC-312, COSMIC-313, COSMIC-021, CONTACT-01, CONTACT-02, CONTACT-03, or our early-stage trials evaluating XL092, XL102 and other product candidates to the extent they may incorporate additional therapies that must be administered via professional intravenous infusion, limited patient movement or interrupted healthcare services at medical institutions have delayed in some instances, and may continue to delay or prevent, on-site infusion of the therapies being evaluated in combination with cabozantinib. If a sizable portion of patients in our combination studies are unable or unwilling to receive all components of the combination therapy being tested in accordance with the applicable clinical trial protocol, it could cause those studies to be delayed, suspended or prevented from producing statistically significant results. Depending upon the duration and severity of the COVID-19 pandemic, we could also experience delays in the commencement of new clinical trials of cabozantinib, or our earlier-stage investigative product candidates. The COVID-19 pandemic could also impede clinical operations and delay our planning and preparation timelines for new clinical trials, as well as adversely affect our ability to obtain regulatory approval for clinical protocols and increase the operating expenses associated with these new clinical trials.

In addition, the COVID-19 pandemic caused us to suspend drug discovery work in our laboratories temporarily while we observed the shelter in place orders issued by the State of California and Alameda County. We also experienced some modest delays with respect to the portion of drug discovery work outsourced to third-party contractors in regions first impacted by COVID-19. While both drug discovery work in our laboratories and outsourced drug discovery activities have since partially resumed, we may be unable to maximize the potential of these programs due to reduced staffing and the imposition of increased safety protocols, and should the COVID-19 pandemic continue to grow in severity, we may have to further scale back or suspend activities in the future. For example, as a result of spikes or surges in infection, positivity or hospitalization rates, or emergence of new SARS-CoV-2 variants, we may choose or be required to suspend work in our laboratories, which will once again impede our drug discovery efforts. With respect to the preclinical development work and drug discovery activities outsourced to third-party contractors, the COVID-19 pandemic could again impede these third parties from providing timely deliverables to us in the future. In addition, should we experience delays in the construction of new laboratory facilities due to the COVID-19 pandemic, our ability to expand our drug discovery activities may be impaired. Should the COVID-19 pandemic be further prolonged or grow in severity, we may ultimately be unable to achieve our drug discovery and preclinical development objectives within the previously disclosed timelines, which could have a material adverse impact on our prospects for growth.

While we believe that our commercial business has, to date, only experienced a modest impact related to the COVID-19 pandemic, it remains possible that over a longer period, changes to our standard sales and marketing practices, including any shifts from in-person back to primarily telephonic and virtual interactions with healthcare professionals, could negatively impact the flow of important information regarding our medicines, which along with obstacles to patient access to healthcare professionals, could diminish sales of our marketed products.

Although as of the date of this Quarterly Report on Form 10-Q, we continue to maintain substantial safety stock inventories for our drug substance and drug products and have not experienced production delays or seen significant impairment to our supply chain as a result of the COVID-19 pandemic, our third-party contract manufacturers and suppliers could experience operational delays due to facility closures and other hardships as a result of the COVID-19 pandemic, which could impact our supply chain by potentially causing delays to or disruptions in the supply of our commercial or clinical products or product candidates. These delays or disruptions could be further exacerbated if the COVID-19 pandemic begins to impact essential distribution systems, which could substantially increase delivery times and costs, or otherwise adversely affect our ability to provide our products to customers and clinical trial sites and generate product revenues.

In response to the COVID-19 pandemic, we have taken numerous temporary precautions to help mitigate the risk of transmission of the virus, including: reducing the number of our employees working on-site at our Alameda headquarters under enhanced safety and social distancing protocols; suspending all non-essential business travel for our employees; and partially limiting the circumstances under which our field employees may engage in in-person promotional activities with healthcare professionals. Over a longer period, these measures could delay our research and development programs, reduce engagements with potential prescribers for our products, and impede our ability to execute on our long-term

business plans. Further, extended periods of remote work could impede the focused attention of management or reduce the productivity of teams that would otherwise be working closely together.

In addition, as a result of broad economic shifts during and as a consequence of efforts to address unemployment and other negative economic effects of the COVID-19 pandemic, we may experience further reductions in the net price of our products. For example, there may be a substantial shift from private health insurance coverage to government insurance coverage, or additional downward pressure on the prices government purchasers will pay for our products due to significant increases in government debt incurred in connection with relief efforts, as well as significant increases in demand for our patient assistance and/or free drug program or other impacts that may not be foreseeable, all or any of which would adversely affect our product revenues.

While we expect the COVID-19 pandemic to continue to have varying degrees of adverse impact on our business operations and, potentially in the future, our financial results, the extent of such adverse impact will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic and resulting disruptions to normal business and personal activities in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease, including the rate at which vaccinations are made available and the percentage of the population that becomes vaccinated. These continuing or future effects could materially and adversely affect our business, financial condition, results of operations and growth prospects, and exacerbate the other risks and uncertainties described elsewhere in this ‘‘Risk Factors’’ section.

If we are unable to manage our growth, there could be a material adverse impact on our business, financial condition and results of operations, and our prospects may be adversely affected.

We have experienced and expect to continue to experience growth in the number of our employees and in the scope of our operations, in particular as we continue to expand the cabozantinib franchise into new indications and grow our pipeline of product candidates. This growth places significant demands on our management and resources, and our current and planned personnel and operating practices may not be adequate to support our growth. To effectively manage our growth, we must continue to improve existing, and implement new, facilities, operational and financial systems, and procedures and controls, as well as 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 plan to increase our management personnel to oversee our expanding operations, and recruiting and retaining qualified individuals is difficult. If we are unable to manage our growth effectively, including as a result of the COVID-19 pandemic or otherwise, or we are unsuccessful in recruiting qualified management personnel, there could be a material adverse impact on our business, financial condition and results of operations.

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

We are highly dependent upon the principal members of our management, as well as clinical, commercial and scientific staff, the loss of whose services might adversely impact the achievement of our objectives. Also, we may not have sufficient personnel to execute our business plans. Retaining and, where necessary, recruiting qualified clinical, commercial, scientific and pharmaceutical operations personnel will be critical to support activities related to advancing the development program for the cabozantinib franchise and our other product candidates, successfully executing upon our commercialization plan for the cabozantinib franchise and our proprietary research and development efforts. Competition is intense for experienced clinical, commercial, scientific and pharmaceutical operations 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. Similarly, the COVID-19 pandemic could negatively impact the health of key personnel or make it difficult to recruit qualified personnel for critical positions. Further, all of our employees are employed “at will” and, therefore, may leave our employment at any time.

Risks Related to Environmental and Product Liability

We use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous materials, including chemicals and biological materials, and our operations can produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge, or any resultant injury from these materials, and we may face liability under applicable laws for any injury or contamination that results from our use or the use by our collaboration partners or other

third parties of these materials, and such liability may exceed our insurance coverage and our total assets. In addition, we may be required to indemnify our collaboration partners against all damages and other liabilities arising out of our development activities or products produced in connection with our collaborations with them. Moreover, our continued compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

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 collaboration partners develop or commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our products and product candidates, injury to our reputation, withdrawal of patients from our clinical trials, product recall, substantial monetary awards to third parties and the inability to commercialize any products that we may develop in the future. We maintain limited product liability insurance coverage for our clinical trials and commercial activities for cabozantinib. However, our insurance 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.

Risks Related to Our Common Stock

Our stock price has been and may in the future be highly volatile.

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

- the announcement of FDA or other regulatory approval or non-approval, or delays in the FDA or other regulatory review process with respect to cabozantinib, our collaboration partners' product candidates being developed in combination with cabozantinib, or our competitors' product candidates;
- the commercial performance of both CABOMETYX and COMETRIQ and the revenues we generate from those approved products, including royalties paid under our collaboration and license agreements;
- adverse or inconclusive results or announcements related to our or our collaboration partners' clinical trials or delays in those clinical trials;
- the timing of achievement of our clinical, regulatory, partnering, commercial and other milestones for the cabozantinib franchise or any of our other programs or product candidates;
- our ability to make future investments in the expansion of our pipeline through drug discovery, including future research collaborations, in-licensing arrangements and other business development activities;
- our ability to obtain the materials and services, including an adequate product supply for any approved drug product, from our third-party vendors or do so at acceptable prices;
- the timing and amount of expenses incurred for clinical development and manufacturing of cabozantinib;
- actions taken by regulatory agencies, both in the U.S. and abroad, with respect to cabozantinib or our clinical trials for cabozantinib;
- unanticipated regulatory actions taken by the FDA as a result of changing FDA standards and practices concerning the review of product candidates, including approvals at earlier stages of clinical development or with lesser developed data sets and expedited reviews;
- the announcement of new products or clinical trial data by our competitors;
- the announcement of regulatory applications, such as MSN's and Teva's respective ANDAs, seeking approval of generic versions of our marketed products;
- quarterly variations in our or our competitors' results of operations;
- changes in our relationships with our collaboration partners, including the termination or modification of our agreements, or other events or conflicts that may affect our collaboration partners' timing and willingness to develop, or if approved, commercialize our products and product candidates out-licensed to them;
- the announcement of an in-licensed product candidate or strategic acquisition;
- litigation, including intellectual property infringement and product liability lawsuits, involving us;

- changes in earnings estimates or recommendations by securities analysts, or financial guidance from our management team, and any failure to achieve the operating results projected by securities analysts or by our management team;
- the entry into new financing arrangements;
- developments in the biotechnology, biopharmaceutical or pharmaceutical industry;
- sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;
- additions and departures of key personnel or board members;
- the 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, such as the impact of the COVID-19 pandemic on financial markets.

These and other factors could have material adverse impact on 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. Likewise, as a result of significant changes in U.S. or global political and economic conditions, including the effects of the COVID-19 pandemic, policies governing foreign trade and healthcare spending and delivery, or future potential U.S. federal government shutdowns, the financial markets could continue to experience significant volatility that could also continue to 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 the attention of management, which could have a material adverse impact on our business, financial condition and results of operations.

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

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

- a prohibition on actions by our stockholders by written consent;
- 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; and
- advance notice requirements for director nominations and stockholder proposals.

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

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.1	3/10/2010	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.2	3/10/2010	
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	8-K	000-30235	3.1	5/25/2012	
3.4	Certificate of Change of Registered Agent and/or Registered Office of Exelixis, Inc.	8-K	000-30235	3.1	10/15/2014	
3.5	Certificate of Ownership and Merger Merging X-Ceptor Therapeutics, Inc. with and into Exelixis, Inc.	8-K	000-30235	3.2	10/15/2014	
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	8-K	000-30235	3.1	5/23/2019	
3.7	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	3/3/2021	
4.1	Specimen Common Stock Certificate	S-1, as amended	333-96335	4.1	4/7/2000	
10.1*	Collaboration and License Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS					X
10.2*	First Amendment dated December 20, 2016, to the Collaboration and License Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS					X
10.3*	Second Amendment dated September 14, 2017, to the Collaboration and License Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS					X
10.4*	Third Amendment dated October 26, 2017, to the Collaboration and License Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS					X

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
10.5*	Supply Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS					X
10.6*	First Amendment dated October 26, 2017, to the Supply Agreement dated February 29, 2016, by and between Exelixis, Inc. and Ipsen Pharma SAS					X
31.1	Certification of Principal Executive Officer Pursuant to Exchange Act Rules 13a-14(a) and Rule 15d-14(a)					X
31.2	Certification of Principal Financial Officer Pursuant to Exchange Act Rules 13a-14(a) and Rule 15d-14(a)					X
32.1‡	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350					X
101.INS	XBRL Instance Document	The XBRL instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File	Formatted as Inline XBRL and contained in Exhibit 101.				

* Portions of this exhibit have been omitted as being immaterial and would be competitively harmful if publicly disclosed.

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

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 6, 2021
Date

By: /s/ Christopher J. Senner
Christopher J. Senner
Executive Vice President and Chief Financial Officer
(Duly Authorized Officer and Principal Financial and Accounting Officer)

Exhibit 10.1

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (the "**Agreement**") is entered into as of February 29, 2016 (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 Ipsen Pharma SAS, a French corporation having an address at 65 Quai Georges Gorse, 92100 Boulogne-Billancourt, France ("**Licensee**"). Exelixis and Licensee 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, Licensee, a fully-integrated pharmaceutical company, possesses substantial resources and expertise in the development and commercialization of pharmaceutical products; and

WHEREAS, Licensee 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 Licensee providing input and support in order for Exelixis and Licensee to collaborate and pursue such development as the Parties agree; Licensee will obtain the exclusive rights to commercialize cabozantinib outside the U.S., Canada, and Japan and will have primary responsibility for the commercialization of cabozantinib outside the U.S., Canada, and Japan as well as development responsibility outside the U.S., Canada and Japan; and, Exelixis will manufacture and supply cabozantinib for all development and commercialization activities by the Parties;

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 Licensee hereby agree as follows:

1. DEFINITIONS

1.1 "**Additional Markets**" means [*].

1.2 "**Affiliate**" means, 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.

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, ordinances, judgments, decrees, directives, injunctions, orders, permits (including MAAs) of or from any court, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item.

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

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

1.6 "**Clinical Trial**" or "**Clinical Trials**" means Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial or Phase 4 Clinical Trial as the context dictates.

1.7 "**cGCP**" shall mean 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, (iii) EU Directive 2001/20/EC and related guidelines, and (iv) the equivalent law or regulation in any other applicable jurisdiction in the Territory.

1.8 "**cGLP**" shall mean 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.

1.9 "**cGMP**" shall mean the current minimum standards for methods to be used in, and the facilities or controls 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, (ii) Directive 2003/94/EC, (iii) Volume 4, Rules Governing Medicinal Products in the EU, Part I and II, in each case, as amended from time to time, and (iv) equivalent law or regulations in any other applicable jurisdiction in the Territory.

1.10 "**Cometriq**" means that certain pharmaceutical product containing the Compound in capsule formulation and known as Cometriq®, which has been developed and commercialized by Exelixis as of the Effective Date for the treatment of progressive, metastatic medullary thyroid cancer (MTC).

1.11 "**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 Licensee Territory, including sales force efforts, detailing, advertising, market research, market access (including 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.

1.12 "**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 without a royalty obligation to others, 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 (but not taking into account any payment owed to the other Party under this Agreement), and all other relevant factors, including technical, legal, scientific and/or medical factors. Commercially Reasonable Efforts requires that a Party: (i) at a minimum establish a plan to achieve objectives and assign specific responsibilities for the achievement of that plan and (ii) make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

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

1.14 "**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, VEGFR2, Ret or any combination of these targets; and (b) which directly binds and modulates the activity of: (i) VEGFR2; (ii) cMET; and/or (iii) Ret, [*].

1.15 "**Compound**" means cabozantinib, having the chemical structure set forth in **Exhibit A**, including [*].

1.16 "**Confidentiality Agreement**" means that certain Confidential Disclosure Agreement between Exelixis and Licensee dated as of February 10, 2015.

1.17 "**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,

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discoveries, inventions, data, designs or formulae in relation to this Agreement; provided that all Exelixis Technology will be deemed Exelixis' Confidential Information, all Licensee Technology will be deemed Licensee's Confidential Information, and all Joint Inventions and Joint Patents will be deemed both Parties' Confidential Information.

1.18 "**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.

1.19 "**Cost of Goods**" means, with respect to any Compound or Product, the fully burdened cost to manufacture such Compound or Product, which means: (a) in the case of [*]; and (b) in the case of [*]. Actual unit costs shall consist of [*]. Direct material costs shall include the [*]. Direct labor costs shall include the cost of: [*]. Manufacturing [*] shall include [*].

1.20 "**Data**" means any and all scientific, technical, test, marketing or sales data pertaining to any Product that is generated by or on behalf of Exelixis, Licensee, their respective Affiliates and Sublicensees, including research data, clinical pharmacology data, pre-clinical data, clinical data, clinical study reports or submissions made in association with an IND or MAA with respect to any Product.

1.21 "**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 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 all regulatory affairs related to any of the foregoing. "**Develop**" and "**Developing**" have correlative meanings.

1.22 "**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 out-of-pocket costs incurred by or on account of a Party in performing Development in accordance with the GDP.

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1.23 "**Drug Master File**" means any (a) drug master files filed with the FDA with respect to the Product, (b) active substance master file (ASMF) filed with the EMA, and (c) equivalent filing in other countries in the Licensee Territory.

1.24 "**EMA**" means the European Medicines Agency or its successor.

1.25 "**EU**" means the European Economic Area and Switzerland.

1.26 "**Executive Officers**" the Chief Executive Officer of Exelixis and the Chief Executive Officer of Licensee.

1.27 "**Exelixis Know-How**" means all Know-How that Exelixis 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 the Licensee Territory. The Exelixis KnowHow includes the Exelixis Data.

1.28 "**Exelixis Patents**" means all Patents in the Licensee Territory that Exelixis 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 or sale of any Compound or Product in the Field in the Licensee 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 B**.

1.29 "**Exelixis Technology**" means the Exelixis KnowHow and the Exelixis Patents, including Exelixis' interest in the Joint Inventions and Joint Patents.

1.30 "**Exelixis Territory**" means the U.S., Canada, and Japan.

1.31 "**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.

1.32 "**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).

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

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

1.35 "**Field**" means all indications and uses in humans and animals.

1.36 "**First Commercial Sale**" means, on a Product-by-Product and country-by-country basis, the earlier of (i) the First Commercial RCC Sale or (ii) first sale by Licensee or any of its Affiliates or Sublicensees to a Third Party for end use of Cometriq for the MTC indication in a given country in the Licensee Territory after Regulatory Approval has been granted with respect to such Product in such country.

1.37 "**First Commercial RCC Sale**" means, on a Product-by-Product and country-by-country basis, the first sale by Licensee or any of its Affiliates or Sublicensees to a Third Party for end use of a Product in a given country in the Licensee Territory after Regulatory Approval has been granted with respect to such Product in such country for the first indication approved by the relevant Regulatory Authority in the treatment of RCC (e.g., 2nd line therapy for RCC).

1.38 "**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 avoidance of doubt, the hours spent by Exelixis temporary workers and contractors on applicable activities may be treated as FTE on a pro-rata basis, but the hours allocated to the work of general corporate or administrative personnel shall not be incorporated into FTE.

1.39 "**FTE Rate**" means an initial rate of (a) with respect to Exelixis' personnel, [*] Dollars ($[*]) per FTE per year and (b) with respect to Licensee's personnel, [*] Euros (€[*]), which rate shall apply through December 31, 2016. Thereafter, the FTE Rate shall be changed annually on a Calendar Year basis to reflect any year-to-year percentage increase or decrease (as the case may be) (i) with respect to Exelixis, 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**"), and (ii) with respect to Licensee, in the French consumer price index as published by the French National Institute of Statistics and Economic Studies ("INSEE") available at insee.fr (both changes based on the change in the CPI from the most recent applicable index available as of the Effective Date to the most recent applicable index available as of the date of the calculation of such revised FTE Rate).

1.40 "**Future Exelixis Licensee**" means any licensee or Sublicensee of Exelixis (other than Licensee) to which a license or a sublicense with respect to Products is granted by Exelixis for all or any portion of the Exelixis Territory (*e.g.*, the U.S., Canada and/or Japan) or will be granted after the Effective Date.

1.41 "**Generic Product**" means, with respect to a Product in a particular regulatory jurisdiction, any pharmaceutical product that (a) contains the same active pharmaceutical ingredient(s) as such Product; (b) is approved by the Regulatory Authority in such country 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;

and (c) is sold in such jurisdiction by a Third Party that is not a Sublicensee and did not purchase such product in a chain of distribution that included any of Exelixis, Licensee, or their respective Affiliates, licensees, or sublicensees.

1.42 "**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).

1.43 "**HCC**" means hepatocellular carcinoma.

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

1.45 "**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.

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

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

1.48 "**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, developing, Products. Know-How excludes Patents and manufacturing know-how of Compound or Product.

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

1.50 "**Licensee Patents**" means all Patents that Licensee 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 or sale of any Compound or Product

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(considering patent applications to be issued with the then-pending claims and considering Joint Patents as if owned solely by Licensee or its Affiliate).

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

1.52 "**Licensee Territory**" means the world outside the Exelixis Territory.

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

1.54 "**MAA Approval**" means approval of an MAA by the applicable Regulatory Authority for marketing and sale of a Product in the applicable country or jurisdiction, but excluding any pricing and/or reimbursement approval.

1.55 **"Major Market Countries"** means [*].

1.56 "**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) the evaluation of applications submitted to Licensee for support of investigator-initiated trials.

1.57 "**MTC**" means medullary thyroid cancer.

1.58 "**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 Licensee and its Affiliates and Sublicensees to Third Parties, less the following deductions to the extent included in the gross invoiced sales price for such Product or otherwise directly paid or incurred by Licensee 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

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applied disproportionately to such Product when compared to the other products of Licensee 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

(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) 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 country in which such sale or other disposition occurred 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 such country).

In no event will any particular amount identified above be deducted more than once in calculating Net Sales. Sales of a Product between Licensee 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, 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 shall not be included in the computation of Net Sales, so long as Licensee, its Affiliates, and Sublicensees do not receive payment for such Product in excess of the Cost of Goods of such Product.

1.59 "**NSCLC**" means non-small cell lung cancer.

1.60 "**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.

1.61 "**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.

1.62 "**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.

1.63 "**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 applications for Regulatory Approval to the competent Regulatory Authorities.

1.64 "**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, post-marketing surveillance trials, and any such trials conducted as part of an Expanded Access Program.

1.65 "**Pricing and Reimbursement Approval**" means, with respect to a Product, the approval, agreement, determination or decision of any Governmental Authority establishing the 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.

1.66 "**Product**" means any pharmaceutical product containing the Compound as an active ingredient, in any form, presentations, dosage or formulation, including but not limited to Cometriq. 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 product, if any, containing the same set of active agents shall be considered the same Product.

1.67 "**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.

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

1.69 "**Region**" means, individually and collectively, the following regions: [*].

1.70 "**Regulatory Approval**" means any and all approvals (including MAA Approval, and Pricing and Reimbursement Approval, if applicable), licenses, registrations, permits, notifications and authorizations (or waivers) of any Regulatory Authority that are necessary for

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the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of a Product in any country or jurisdiction.

1.71 "**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 EMA. For countries where governmental approval is required for pricing or reimbursement for a pharmaceutical product to be reimbursed by national health insurance (or its local equivalent), Regulatory Authority shall also include any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

1.72 **"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 outside the U.S., such as Directive 2001/83/EC (as amended) in the EU.

1.73 "**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.

1.74 "**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.

1.75 "**SEC**" means the U.S. Securities and Exchange Commission, or any successor entity or its foreign equivalent such as the French *Autorités des Marchés Financiers* or otherwise, as applicable.

1.76 "**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.

1.77 "**Stockout Period**" means a period during which Licensee, as a result of failure of Exelixis to supply Product, has no commercial inventory available to supply the market in the Licensee Territory. Inventory stockouts arising from Licensee's failure to maintain the [*] safety stock in accordance with the Supply Agreement shall not give rise to a Stockout Period.

1.78 "**Sublicensee**" means a Third Party to whom Licensee grants a sublicense to Develop, use, import, promote, offer for sale or sell any Product in the Field in the Licensee Territory, beyond the mere right to purchase Products from Licensee and its Affiliates, and excluding wholesalers, full-service distributors that do not promote the sale of the Product, and

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other similar physical distributors. In no event shall Exelixis or any of its Affiliates be deemed a Sublicensee.

1.79 "**Third Party**" means any entity other than Exelixis or Licensee or an Affiliate of Exelixis or Licensee.

1.80 "**Tier 1 Additional Indication**" means RCC (1st line), HCC (1st line), [*].

1.81 "**Tier 2 Additional Indication**" means any line of therapy for [*].

1.82 "**Top 5 EU**" means the United Kingdom, Germany, France, Spain, and Italy.

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

1.84 "**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 [*].

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

Defined Terms	**Section**
Acquisition Transaction	17.8(b)
Alliance Manager	3.8
Allowable Increases	4.5(b)
Auditor	10.4
Beneficial Party	9.2(e)
Change of Control	2.9(b)
Claim	13.3
Commercialization Plan	6.2
Competing Program	2.9(a)
Compound Invention	11.1(b)(i)
Development Budget	4.2
Disputed Matter	16.2
Divest	2.8(c)
Excess Funds	4.5(a)
Exelixis Data	11.1(a)
Exelixis Entity	17.8(a)(i)(1)

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Exelixis Indemnitee	13.2
Exelixis Only Development Work	4.5(e)
Global Development Plan or GDP	4.2
Indemnitee	13.3
Indemnitor	13.3
Independent Work	4.3
Independent Work Cost	9.2(c)
Initial Committed Studies	4.5(a)
Injunctive Relief	16.3(b)
Licensee Data	11.1(a)
Licensee Indemnitee	13.1
Licensee Only Development Work	4.5(e)
Joint Commercialization Committee or JDC	3.3
Joint Development Committee or JDC	3.2
Joint Steering Committee or JSC	3.1
Joint Inventions	11.1(b)(ii)
Joint Patents	11.1(b)(ii)
Losses	13.1
Materials	4.14
PV Costs	5.5
Pharmacovigilance Agreement	5.6
Product Infringement	11.3(a)
Product Marks	11.7(a)
Promotional Materials	6.4(c)
Recall	5.10
Regulatory Meeting	5.4
Royalty Term	9.5(c)
Sales Forecast	6.3(b)
Sobi	5.2
Sobi Agreement	8.1
Sole Inventions	11.1(b)(ii)
Standstill Period	17.8(a)
Sunshine Reporting Laws	5.11
Supply Agreement	7.1
Supply Contacts	3.9
Term	15.1
TMC	5.2
Withholding Tax Action	10.3(c)

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2. GRANT OF LICENSES

2.1 Licenses Granted to Licensee. Subject to the terms and conditions of this Agreement (including Section 8.1), Exelixis hereby grants to Licensee, during the Term:

(a) an exclusive (even as to Exelixis, except as expressly set forth herein), 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 Licensee Territory; and

(b) a non-exclusive license, 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 on a worldwide basis under the GDP, and to use the Products for that purpose. Exelixis agrees not to grant any further license to Develop the Products except to Future Exelixis Licensees.

2.2 Sublicenses. Licensee shall have the right to grant sublicenses under the licenses granted in Section 2.1:

(a) to an Affiliate of Licensee without Exelixis' express prior written consent and without providing any written notice to Exelixis, *provided that* such sublicense will terminate if such sublicensee no longer qualifies as an Affiliate of Licensee.

(b) to any Third Party distributor identified on **Exhibit C** attached hereto (which list of approved distributors shall be agreed upon by the Parties within thirty (30) days following the Effective Date) without Exelixis' express prior written consent, *provided that* Licensee does not have an Affiliate that is then engaged in selling pharmaceutical products in such sublicensed territory.

(c) to any Third Party distributor not listed in **Exhibit C** without Exelixis' express prior written consent, *provided that* (i) Licensee does not have an Affiliate that is then engaged in selling pharmaceutical products in such sublicensed territory; (ii) Licensee has conducted a reasonable investigation of such Third Party and believes that such Third Party is qualified and competent, and such Third Party annually certifies its compliance with, and actually complies with, Applicable Laws and other applicable requirements, (iii) such Third Party is then engaged in the promotion and commercialization of oncology products, and (iv) Licensee is then using such Third Party for distribution of pharmaceutical products other than Products; and *provided further that* Licensee notifies Exelixis in writing [*] days' in advance of granting such sublicense specifying (x) the name of such Third Party and the country(ies) such sublicense will cover, and (y) that Licensee has met the conditions set forth in (ii) – (iv). If Exelixis believes Licensee should not grant such sublicense to such Third Party, it may direct such concern and any documentation supporting such concern to the JSC for discussion.

(d) to a Third Party other than as set forth in (b) and (c) with Exelixis' express prior written consent.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

All sublicenses granted under the licenses granted in Section 2.1 shall be 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, including any distributor) shall not further sublicense except with the consent of Licensee and Exelixis. Licensee 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 Licensee. Licensee shall be responsible for the compliance of its Affiliates, Sublicensees (for clarity, including any distributors), and subcontractors with the terms and conditions of this Agreement. Licensee shall provide written notice to Exelixis of each sublicense granted to a Third Party hereunder, specifying the name of the Sublicensee, the territory, and the duration of the sublicense.

Licensee agrees that in countries where it is not Commercializing Products through its Affiliates, it will only contract with Third Party distributors who satisfy the conditions of paragraphs (b), (c), or (d) above, whether or not a sublicense of rights hereunder is actually required.

2.3 Reserved Rights. Exelixis hereby expressly reserves:

(a) the right under 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 Licensee 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, Licensee hereby grants to Exelixis:

(a) an exclusive (even as to Licensee, except as expressly set forth herein), royalty-free, fully paid-up license, with the right to sublicense (provided that any such sublicensee may only grant a further sublicense at two tiers), under the Licensee Technology to use, sell, offer for sale, import and otherwise Commercialize the Products in the Field in the Exelixis Territory;

(b) a co-exclusive, royalty-free, fully paid-up license, with the right to sublicense (provided that any such sublicensee may only grant a further sublicense at two tiers), under the Licensee Technology to Develop the Compound and Products on a worldwide basis under the GDP; and

(c) an exclusive (even as to Licensee), royalty-free, fully paid-up license, with the right to sublicense (provided that any such sublicensee may only grant a further sublicense at

two tiers), under the Licensee Technology to make and have made the Compound and Products anywhere in the world.

(d) Sublicenses: Exelixis shall have the right to grant sublicenses under the licenses granted in Section 2.4

(1) without Licensee's consent and without providing any written notice to Licensee if such sublicense is granted to an Affiliate; and

(2) without Licensee's prior written consent, *provided* however that a written notice is sent to Licensee for Licensee's information if such sublicense is granted to Third Parties to manufacture the Product and *provided further that* such Third Party is qualified and certified to manufacture the Product in such country in accordance with Applicable Laws and other applicable requirements.

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.

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 Licensee, in electronic form where, all Exelixis Know-How that comes into existence after the Effective Date and that was not previously provided to Licensee, 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, Licensee shall and shall cause its Affiliates to, without additional compensation, disclose and make available to Exelixis, in electronic form where possible, any Licensee Know-How not previously provided to Exelixis, and promptly after the earlier of the development, making, conception or reduction to practice of such Licensee 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 Know-How or Patents that are necessary or reasonably useful to Develop, use, sell, offer for sale or import the Products in the Field and in the Licensee Territory, then Exelixis shall notify Licensee, identifying the relevant Know-How or Patents, by providing Licensee with the substantive terms of the applicable Third Party license agreement to Licensee, to the extent applicable to the rights that would be sublicensed to Licensee, which Exelixis hereby agrees to do. Such Know-How and Patents, to the extent falling within the definition of Exelixis Technology, will be sublicensed to Licensee if Licensee provides Exelixis with written notice in which (i) Licensee consents to

adding such Patents and Know-How to the definition of Exelixis Technology, (ii) Exelixis and Licensee, acting reasonably in good faith, agree on the terms and conditions of the payments that would be owed under such license agreement as a result of Exelixis' granting a sublicense to Licensee or Licensee's practice thereunder, including Licensee's and its Affiliates' and Sublicensees' Development, use, sale, offer for sale and importation of the Compound and Products in the Field and in the Licensee Territory, and a reasonable allocation of all other payments under such license agreement, and to make all payments when due and provide all reports required under such license agreement; and (iii) Licensee acknowledges in writing that its sublicense under such license agreement is subject to the terms and conditions of such license agreement.

(b) Licensee shall promptly notify Exelixis if it becomes aware of any Third Party Know-How or Patents that are necessary or reasonably useful to Develop, make, have made, use, sell, offer for sale or import the Compound and Products in the Field, and shall give Exelixis the first right to negotiate and obtain a license from such Third Party under such Know-How or Patents. Except with the prior written consent of the other Party, neither Party shall obtain a license to Third Party Patents or Know-How that is necessary or reasonably useful to Develop, make, have made, use, sell, offer for sale or import the Products, for use with the Products in the other Party's territory, unless it obtains the right to sublicense such rights to the other Party.

2.8 Exclusivity.

(a) Subject to Section 2.8(c) below, for the period starting from the Effective Date and for ten (10) years following the first Regulatory Approval of the Product in the first indication other than MTC, neither Party (nor any of its Affiliates) shall, directly or indirectly (including through a Third Party), commercialize any Competing Product for therapeutic or prophylactic use (a "**Competing Program**").

(b) Subject to Section 2.8(c) below, for the period starting from the Effective Date and for five (5) years following the first Regulatory Approval of the Product in the first indication other than MTC, neither Party (nor any of its Affiliates) shall, directly or indirectly (including through a Third Party) develop any Competing Program [*].

(c) 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 conduct of a Competing Program:

(i) if such transaction constitutes a Change of Control of [*], [*] shall have the right to terminate the Agreement as provided herein. [*] shall have [*] following the announcement of such transaction to give written notice to [*] of its intent to terminate the Agreement, such termination to be effective [*] after receipt of notice of termination (but only after completion of the transaction with such entity having a Competing Product) unless [*] notifies [*] within [*] of receipt of the notice of termination of its decision to (a) Divest any such Competing Product to a Third Party, (b) discontinue the

Competing Program, or (c) acting reasonably and in good faith agree with [*] and such assignee or new Affiliate to find a mutually acceptable agreement whereby they can, on compliance with Applicable Laws, jointly exploit such Competing Product together with the Product. Such disposition shall be completed within [*] of completion of any such sale or Change of Control transaction. During the [*], 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 such Party's 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. In the event this Agreement is terminated in accordance with the foregoing, neither Party shall [*];

(ii) if such transaction constitutes a Change of Control of [*], then such assignee or new Affiliate shall continue to Develop and Commercialize the Product using a level of Commercially Reasonable Efforts that assumes the Competing Program was not acquired and shall, within [*] after the closing of such Change of Control transaction: (a) Divest the Competing Program to a Third Party, or (b) discontinue the Competing Program. During the [*] period, such assignee or new Affiliate (as the case may be) 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 and shall not use any [*] in the conduct of the Competing Program;

(iii) if such transaction does not constitute a Change of Control of such Party, then such Party and its new Affiliate shall have [*] from the closing date of such transaction to wind down or complete the Divesture of the Competing Program; during this period, the Party's conduct of the Competing Program shall not deemed a breach of the exclusivity obligations set forth above, provided that the Party continues to fulfill its obligations under this Agreement in all respects, conducts its Competing Program activities independently of the activities pursuant to this Agreement and does not use: (A) any [*] or (B) [*], in each case in the conduct of such Competing Program. For clarity, if such Party completely winds down the Competing Program within the [*] time period, it shall be allowed to divest the Competing Program later, provided that it does not restart the Competing Program.

As used in this Section 2.8(c), "**Change of Control**" means, with respect to a Party: (1) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (2) a person or entity, or group of persons or entities acting in concert, acquire more than fifty percent (50%) of the voting equity securities or management control of such Party; and "**Divest**" means the sale or transfer of rights to the Competing Program to a Third Party without receiving a continuing share of profit, royalty payment or other economic interest in the success of such Competing Program.

(d) During the Term of this Agreement, neither Party (nor any of its Affiliates) shall, directly or indirectly (including through a Third Party), commercialize the Product or any Generic Product of any Product in the other party's territory.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3. Governance

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

(a) provide a forum for discussion of the Development and Commercialization of the Compound and Products in the Licensee Territory and the Exelixis Territory;

(b) review and approve the global strategy for the Development of the Product worldwide and 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 Licensee Territory, including proposed amendments, following recommendation by the JCC;

(d) review and approve Sales Forecasts (and corrective plans, if any) submitted by Licensee pursuant to Section 6.3(c), following recommendation by the JCC;

(e) review the manufacturing and supply strategy, supply performance and Cost of Goods, including periodic review of worldwide order forecasts for the Product to avoid supply shortage and unfavorable treatment of Licensee's supply requirements disproportionate to those of Exelixis and Future Exelixis Licensees on the basis of their respective volumes;

(f) review and approve any recommendations of the JCC not to launch (or to significantly delay the launch of) a Product in a particular country of the Licensee Territory;

(g) review and approve coordinated activities under global brand strategies for the Products in each of the Parties' territories, following recommendation by the JCC;

(h) approve decisions of the JDC, JCC and any other joint subcommittee established by JSC, including appointment of memberships, membership changes, and resolving any disputed matter submitted to it by such Committees;

(i) establish additional joint subcommittees as it deems necessary or advisable to further the purpose of this Agreement, including approving establishment and membership of subcommittees if proposed by the JDC or JCC; and

(j) 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.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

For clarity, any information sharing of Commercialization matters regarding the Exelixis Territory shall be for 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 14.4 and 14.5.

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) report to the JSC on all significant Development activities, including implementation of the GDP, and on the activities of the JDC;

(b) coordinate and monitor the Development activities of the Parties under the GDP and oversee implementation of the GDP;

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

(d) elaborate, review and approve 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) in the Exelixis and Licensee Territories and monitor the progress of the clinical studies;

(e) define areas of permissible scientific and medical inquiry and parameters for Phase 4 Clinical Trials in the Exelixis and Licensee Territories;

(f) review Data resulting from Phase 1/1b/2 Clinical Trials against go/no-go criteria in the GDP to determine progression to a Phase 3 Clinical Trial;

(g) review Data resulting from Phase 3 Clinical Trials against go/no-go criteria in the GDP to determine progression to submission of Regulatory Filing;

(h) prepare amendments to the GDP (including the Development Budget) and submit such amendments to the JSC for approval;

(i) monitor and coordinate all regulatory actions worldwide, communications and submissions for the Compound and Products under the GDP and pharmacovigilance and safety matters worldwide;

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

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(k) oversee and coordinate the 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) oversee and coordinate decisions related to research or Development of new indications, characterization and Development of bio-markers (if any), which may be coordinated through a Medical Affairs working group established and overseen by the JDC;

(m) review activities related to pharmaceutical development, Phase 3 Clinical Trial active ingredient and drug product new campaigns (i.e., chemical process scale-up/optimization (if needed) and micronization process study, manufacturing, QC testing and release of GMP batches of active ingredient and drug product as needed for Phase 3 Clinical Trial, in particular, review and approval of the protocols on manufacturing, micronization, scale-up plan and process optimization;

(n) maintain and review the "Company Core Data Sheet", which shall cover material relating to safety, indications, dosing, pharmacology and other information concerning the Product including Company Core Safety Information;

(o) coordinate the supply of the Compound and Products to Licensee for Development use;

(p) oversee and facilitate the Parties' communications and activities with respect to publications under Section 14.4;

(q) establish and supervise the global publication strategy with respect to the Compound and Products;

(r) 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 JSC.

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) report to the JSC on all significant Commercialization activities in the Licensee Territory, including implementation of the Commercialization Plan, and on the activities of the JCC;

(b) review, discuss and approve the Commercialization Plans and related activities with respect to the Commercialization of Products in the Licensee Territory;

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

(d) on an annual basis, review and approve Licensee's Sales Forecast prepared pursuant to Section 6.3(b) as well as any corrective plans submitted thereunder;

(e) review and approve any recommendation by Licensee not to launch (or to significantly delay the launch of) any Product in any country of the Licensee Territory;

(f) review and discuss the major findings of Licensee's market research with respect to any Product in the Licensee Territory;

(g) provide input to the JDC on the global publication strategy with respect to the Products and implement such strategy under supervision of the JDC once it has been established;

(h) review and oversee the branding and product positioning strategy for Products in the Licensee Territory;

(i) establish pricing corridors for Products in the Licensee Territory for the purpose of reimbursement and potential international pricing reference by relevant Regulatory Authorities;

(j) define and coordinate medical messaging worldwide with respect to the Products;

(k) oversee and facilitate the Parties' communications and activities with respect to publications under Section 14.4;

(l) design a global brand strategy for the Licensee Territory (e.g., a four-year brand plan, resource plan, , etc.) and submit such strategy to the JSC for review and approval;

(m) discuss and coordinate the manufacture and supply of the Products to Licensee for Commercial use; and

(n) 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 JSC.

3.4 Executive Committee. Each Party shall designate an appropriate senior executive officer of Exelixis and/or Licensee (e.g., CEO or members of each Party's executive

committee) to meet once a year to discuss strategic issues and other issues that either Party deems important to maintain a successful partnership and collaboration.

3.5 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 prepare and circulate agendas to Committee members at least seven (7) days 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 thirty (30) days of such meeting. The initial members of each of the JSC, 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 and JCC be held less frequently than once every [*], and meetings of the JSC once every [*], during the [*] following the Effective Date and then the Parties may decide to reduce the frequency of the Committee meetings. The first JSC 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 by both Parties at least [*] meetings per year shall be held in person during the first [*] following the Effective Date, and, for the subsequent years of the Term, 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. 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 one (1) representative 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 JSC be convened for the purpose of resolving any disputes in connection with, or for the purpose of reviewing or making a decision pertaining to any material subject-matter within the scope of the JSC, the review or resolution of which cannot be reasonably postponed until the following scheduled JSC meeting. 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 nonvoting 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 or delayed. Such Party

shall ensure that such Third Party is bound by written confidentiality and non-use obligations consistent with the terms of this Agreement.

3.6 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 3.6(c), if such disagreement arose within the JDC or JCC, it shall be referred to the JSC for resolution. If the JSC cannot resolve such matter within [*], or if the disagreement first arose within the JSC, 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 matters, except for:

(1) the addition of [*], the cost of which would be [*]; and,

(2) any material modification to a [*]; for the purpose of this clause, "material modification" means any material changes to the agreed upon [*].

(ii) Licensee shall have the final decision making authority, which shall be exercised in its reasonable discretion, with respect to (1) Commercialization in the Licensee Territory, except with respect to the decision [*] a particular Product in a country, (2) Medical Affairs in the Licensee Territory, and (3) regulatory matters in the Licensee Territory that do not affect the Exelixis Territory; provided that Licensee's decision shall be consistent with the terms and conditions of this Agreement, including without limitation Section 6.4(b) regarding pricing, and Section 6.3(c) regarding sales forecasts.

(iii) Neither Party shall have the final decision making authority with respect to the matters in Sections 3.6(b)(i)(1) and (2) or with respect to the decision not to [*] a particular Product in a particular country [*], and the status quo shall persist with respect to such matter if the Parties are unable to agree.

(c) Notwithstanding Section 3.6(a), [*] representative shall have the deciding vote on all tactical [*] matters for the Products [*], and such matter shall not be subject to escalation to [*]; provided that such decision does not directly affect [*] and such decision shall be consistent with the terms and conditions of this Agreement.

3.7 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.

3.8 Discontinuation of Committees. The activities to be performed by each Committee shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. Each Committee shall continue to exist until the first to occur of: (a) the Parties mutually agree to disband such Committee; or (b) Exelixis provides written notice to Licensee of its intention to disband and no longer participate in such Committee. Once the Parties mutually agree or Exelixis has provided written notice to disband such Committee, such Committee shall have no further obligations under this Agreement and, thereafter, each Party shall designate a contact person for the exchange of information under this Agreement or such exchange of information shall be made through Alliance Managers, and decisions of such Committee shall be decisions as between the Parties, subject to the other terms and conditions of this Agreement.

3.9 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 JSC of all relevant matters raised at the JDC, the JCC and at any joint subcommittees and project teams. Each Alliance Manager shall be permitted to attend meetings of the JSC 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 JSC 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.

3.10 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

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resulting from such collaboration to facilitate the Development of the Compound and Products throughout the Licensee Territory and the Exelixis Territory.

4.2 Development Plan. 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 Licensee Only Development Work, shall be conducted only pursuant to a comprehensive written global Development plan (the "**Global Development Plan**" or "**GDP**"), which shall be incorporated by reference as part of this Agreement. 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 EMA and FDA for MAA Approval of the Compound and Products for RCC, HCC, and other indications agreed upon by the Parties. The GDP may also include any other Development activities approved by the JSC, including parameters for permissible scientific inquiry in Phase 4 Clinical Trials. The GDP will include Clinical Trials that the Parties are committed to conducting (unless modification is required by a Regulatory Authority or any local or regional IRB/ethics committee, or is reasonably necessary to protect patient safety) as well as Clinical Trials that will be decided by the JDC and JSC 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. As of the Effective Date, the Parties have agreed upon an initial GDP and Development Budget, attached to this Agreement as **Exhibit D**. If the terms of the GDP contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern. From time to time during the Term (at least on [*] basis), the JDC shall prepare updates and amendments, as appropriate, to the then-current GDP, including budgets, and shall submit such updates and amendments to the JSC for review and approval before such updates and amendments are adopted. If upon the determination by the JDC as reviewed and approved by the JSC, any pre-clinical, or Clinical Trials not included in the GDP (i) are required in order to obtain and/or maintain MAA Approval for a Product in the EU and in one or all the countries of the Exelixis Territory, or (ii) are otherwise recommended by the EMA or the FDA in the EU and in one or all of the countries of the Exelixis Territory, then the JDC shall review and recommend and the JSC shall review and approve an amendment to the GDP reflecting such additional studies, including associated 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 Licensee Territory (in the case of Licensee) 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

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Proposal, the JDC or delegated team shall meet to review the Proposal and to permit the other Party ("**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. The Parties acknowledge that it is their intent to collaborate in good faith to establish a similar review and approval process with any Future Exelixis Licensee. No additional Development work shall proceed without the approval of the JSC, 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 9.2(b). 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 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(d) and 9.2(b). Notwithstanding the foregoing, following the approval of the Independent Work by the JSC, 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 the JSC; and (C) neither Party shall conduct Independent Work in a manner that would have a material adverse effect on the Products in either Party's territory.

4.4 Annual Update to Development Budget. The JDC shall discuss and agree upon the subsequent year's Development Budget on an annual basis no later than November 1 of each year. The JDC shall report any significant changes in the annual budgets to the JSC for approval at the next scheduled JSC meeting.

4.5 Development Cost.

(a) Committed Studies As Of The Effective Date (Current Budget). Except as set forth in Section 4.5(b) below, Exelixis shall bear one hundred percent (100%) of all Development Costs for the first [*] dollars ($[*]) of Development Costs for all Clinical Trials that are committed studies in the GDP [*] as of the Effective Date ("**Initial Committed Studies**"). Thereafter, except as set forth in Section 4.5(b) below, (i) Exelixis shall bear sixty-five percent (65%) and Licensee shall bear thirty-five percent (35%) of all Development Costs for such Clinical Trials [*] until the aggregate Development Costs of such Clinical Trials equals [*] dollars ($[*]), and (ii) if aggregate Development Costs for such Clinical Trials [*] exceed [*] dollars ($[*]), Exelixis shall bear [*] percent ([*]%) and Licensee shall bear [*] percent ([*]%) of all remaining Development Costs for such Clinical Trials. For Clinical Trials that become committed studies in the GDP after the Effective Date, Exelixis shall bear sixty-five percent (65%) and Licensee shall bear thirty-five percent (35%) of all Development Costs of such Clinical Trials. If Exelixis completes the Initial Committed Studies for an amount less than [*] dollars ($[*]), any amount not spent ("**Excess Funds**") shall be credited against the Parties'

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respective share of Clinical Trials that become committed studies in the GDP after the Effective Date. Without limiting the foregoing, if any [*].

(b) Allowable Increases. Separate from the cost allocation provided for in Section 4.5(a), Exelixis shall bear sixty-five percent (65%) and Licensee shall bear thirty-five percent (35%) of all Allowable Increases in Development Costs for all Clinical Trials that are committed studies in the GDP as of the Effective Date. "Allowable Increases" are defined as increased Development Costs resulting from (i) changes in study design after the Effective Date that are approved by the JDC and JSC [*] (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), and (iii) extensions in the duration of Clinical Trials resulting from a lower than anticipated rate of clinical events or higher rates of survival.

(c) Expanded Access Program 214. Exelixis shall bear the first [*] dollars ($[*]) of Development Costs (excluding the costs of Licensee FTEs and other internal costs of Licensee) associated with Expanded Access Program 214. Licensee shall bear one hundred percent (100%) of its internal costs of such program, inclusive of its FTEs, as well as one hundred percent (100%) of all Development Costs of such program in excess of the [*] dollars ($[*]) borne by Exelixis. If such program is completed for an amount of Development Costs less than [*] dollars ($[*]), no financial adjustment shall be made.

(d) Independent Work Cost. Notwithstanding Section 4.5(a), the Party conducting the Independent Work approved by the JSC under Section 4.3 shall be solely responsible for the Development Costs with respect to such Independent Work, subject to Section 9.2(c).

(e) Country-Specific 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 countries within such Party's Territory, including: (i) any and all country-specific activities (e.g., a Canada or Japan only trial for Exelixis or China only trial for Licensee, Expanded Access Programs); (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). The Development work set forth in this Section 4.5(e) pertaining to Licensee shall be deemed the "**Licensee Only Development Work"** and the Development work set forth in this Section 4.5(e) pertaining to Exelixis shall be deemed the "**Exelixis Only Development Work."** All planned and in-process Licensee Only Development Work and Exelixis Only 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 and the JSC.

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 shall be the Sponsor and have

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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; and (c) Licensee shall be the Sponsor and have the operational responsibility for the Licensee Only Development Work and Exelixis shall be the Sponsor and have the operational responsibility for the Exelixis Only 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 and recruitment, each Party shall inform the other Party within forty-eight (48) hours from knowledge of the occurrence of such event; (ii) supporting documentation (e.g. protocols, CRFs, 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 any Future Exelixis 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 any Future Exelixis 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 all Development under the GDP, including Independent Work (but subject to Section 4.7(b) below), Exelixis Only Development Work and Licensee Only Development Work. Notwithstanding the foregoing, should either Party fail to obtain such use and reference rights from any Sublicensee or Future Exelixis Licensee, such Party shall not have the right to grant use and access or rights to such Sublicensee or Future Exelixis Licensee to any documentation 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 9.2(c).

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. Unless otherwise agreed by the Parties, Exelixis shall be the Sponsor and be responsible for conducting

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all Clinical Trials that are required to obtain MAA Approvals by both the EMA and FDA for RCC, HCC, NSCLC, and other indications in the GDP. In addition, Licensee shall also use Commercially Reasonable Efforts to Develop Licensee Only Development Work and any Licensee Independent Work, file MAAs and seek and maintain Regulatory Approval (including Pricing and Reimbursement Approval, as applicable) for the Products throughout the Licensee 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 promptly provide the other Party (but in no event more than [*] following receipt) 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. 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 14, 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 approval of the JDC.

4.13 Restrictions. After the Effective Date and during the Term, neither Party nor any of its Affiliates or Sublicensees 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, including Phase 4 Clinical Trials conducted pursuant to parameters of scientific inquiry defined in the GDP or otherwise approved by the JDC; or (b) comparative studies of its product versus the Product

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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, Licensee 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.

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, 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 Licensee Territory and Exelixis Territory. The GDP shall also specify which Party shall apply for and hold Regulatory Filings in each country 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 its territory.

(iii) Licensee acknowledges that Exelixis may be required to communicate with Regulatory Authorities in the Licensee Territory as a result of Development

and manufacturing activities in such territory. Exelixis shall notify Licensee as soon as reasonably possible of such communication with Regulatory Authorities and seek to incorporate input from Licensee in preparation for such communication. Exelixis shall then keep Licensee informed of any such communications.

(b) Transfer of Regulatory Filings. Except as set forth in Section 5.2, Exelixis shall, in each case as may be required to enable Licensee to submit and file Regulatory Filings and obtain MAA Approvals for Products in the Licensee Territory:

(i) transfer to Licensee all Regulatory Approvals and Regulatory Filings submitted to any Regulatory Authority in the Licensee Territory for the Compound and Products that are in Exelixis' name and Controlled by Exelixis, other than INDs relating to Clinical Trials conducted and sponsored by Exelixis pursuant to the GDP;

(ii) to the extent that such transfer is not permitted under Applicable Laws, Exelixis shall provide to Licensee a right of reference or use to such Regulatory Approvals and Regulatory Filings. Exelixis shall provide appropriate notification of Licensee's access and reference rights to the applicable Regulatory Authorities (including, to the extent applicable, an informed consent letter under Article 10c of Directive 2001/83/EC as amended), at the expense of Licensee seeking such right of reference. For the purposes of this Agreement, "right of reference" shall mean the "right of reference or use" as defined in 21 C.F.R. §314.3(b) and any equivalent regulation outside the US, including Article 10c of Directive 2001/83/EC, as each may be amended from time to time;

(iii) provide to Licensee copies in electronic form of all Regulatory Approvals and Regulatory Filings submitted to any Regulatory Authority in the Licensee Territory including those related to CMC, manufacturing and product development, validation and manufacturing for the Compound and Products that are in Exelixis' name and Controlled by Exelixis, regulatory dossiers in Exelixis' possession or Control, and the Drug Master File; and

(iv) to the extent any variations to the chemistry, manufacturing, and controls ("**CMC**") section of the Regulatory Filing are required to conform with a variation that is initiated by Exelixis at its sole discretion, Exelixis shall reimburse Licensee for all associated fees that are paid by Licensee in filing such variations; *provided that*, for variations required to comply with Applicable Laws or any requirement of a Regulatory Authority, (a) Exelixis shall remain responsible for submissions and associated fees for all CMC variations originally attributable to a Regulatory Authority in the Exelixis Territory, and (b) Licensee shall be responsible for submissions and associated fees for all CMC variations originally attributable to a Regulatory Authority in the Licensee Territory.

5.2 Existing Arrangements. The Parties acknowledge that as of the Effective Date, Exelixis; its regulatory agent, TMC Pharma Services ("**TMC**"); and its authorized distributor, Swedish Orphan Biovitrum AB ("**Sobi**"), hold certain Regulatory Filings, licenses, and MAA Approvals related to Cometriq for MTC in the EU. Exelixis, and Exelixis on behalf of TMC and Sobi, will ensure that Exelixis, TMC and Sobi will transfer Regulatory Filings, licenses, and MAA Approvals for Cometriq for MTC to Licensee in accordance with Article 8. In addition,

Exelixis holds certain EMA Regulatory Filings, including the EMA MAA filing, for the Product in RCC. As set forth in Section 5.1(b), the Parties shall cooperate to be ready to transfer and assign these EMA Regulatory Filings to Licensee and Exelixis shall notify the EMA promptly after the Effective Date that Licensee shall be the Marketing Authorization Holder as from the date of the transfer of the MAA. The Parties agree to work toward the transfer of MAA holder status to Licensee by [*]. Until the MAA transfer is accepted by the EMA, Exelixis shall be responsible for preparing and filing the MAA for the Product in RCC.

5.3 Regulatory Information Sharing. Each Party shall, upon the other Party's reasonable request, promptly provide the other Party (but in no event more than [*]) with copies of any Regulatory Filings prepared (including any drafts), submitted or received by such Party in the U.S. and the Licensee 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, as applicable, be the following communications/correspondence with the Regulatory Authority: (i) summary of contact reports either Party receives concerning substantive conversations or substantive meetings in its respective territory with the FDA, EMA, CFDA and PMDA with respect to the Product or if contacts with those Regulatory Authorities are made orally, to be reduced in writing, (ii) documents related to regulatory milestones and dates (*e.g.*, submission, validations, agency review questions, CHMP opinion and FDA complete response letter and their equivalent), (iii) IND annual reports and cover letters of all agency submissions relating to the Compound or any Product. If any Regulatory Filing to be provided under this Section 5.3 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 Future Exelixis Licensee. Each of Licensee and Exelixis shall use Commercially Reasonable Efforts to grant the other Party access and rights to use any such communications with any Regulatory Authority generated by or on behalf of any Sublicensee or Future Exelixis Licensee, respectively. Should either Party fail to obtain such access and rights from any Sublicensee or Future Exelixis Licensee, such Party shall not have the right to grant access or rights to such Sublicensee or Future Exelixis Licensee to any such communications with any Regulatory Authority generated by or on behalf of the other Party.

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

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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 Licensee Territory, and Exelixis shall have the right to provide input in preparation for all Regulatory Meetings and, with the consent of Licensee, not to be unreasonably withheld, the right, but not the obligation, to have its representatives attend (but, unless otherwise requested by the other Party, not participate in) the Regulatory Meetings. Licensee shall have these same rights with respect to any such Regulatory Meetings before such Regulatory Filings are transferred to Licensee under Sections 5.1(b) and 5.2.

(a) **Regulatory Inspections**. Licensee shall permit the Regulatory Authority(ies) in the Exelixis Territory to conduct inspections of Licensee, its Affiliates, and acting reasonably and in good faith of Sublicensees or subcontractors (including Clinical Trial sites) relating to the Development of the Product under the GDP, and shall ensure that such Affiliates, and acting reasonably and on good faith, such Sublicensees and subcontractors permit such inspections. In addition, Licensee shall promptly notify Exelixis of any such inspection and shall supply Exelixis with all information pertinent thereto. Licensee shall use Commercially Reasonable Efforts to allow an Exelixis representative to attend any such inspection with the presence of Licensee. Exelixis shall permit the Regulatory Authority(ies) in the Licensee Territory to conduct inspections of Exelixis, its Affiliates, and acting reasonably and in good faith of Sublicensees or subcontractors (including Clinical Trial sites) relating to the Development of the Product under the GDP for the Licensee Territory, and shall ensure that such Affiliates, and acting reasonably and on good faith, such Sublicensees and subcontractors permit such inspections. In addition, Exelixis shall promptly notify Licensee of any such inspection and shall supply Licensee with all information pertinent thereto. Exelixis shall use Commercially Reasonable Efforts to allow a Licensee representative to attend any such inspection with the presence of Exelixis.

5.5 Adverse Event Reporting; Pharmacovigilance Agreement. Within sixty (60) days after the Effective Date, but in any case prior to transfer of the marketing authorization, the Parties shall enter into a pharmacovigilance agreement setting forth the worldwide pharmacovigilance procedures for 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 (including to the extent applicable, those obligations contained in ICH guidelines, E2A, E2B, E2C, E2D and E2F) to monitor the patients' safety. Exelixis has established and shall continue to hold at its costs and expenses the global safety database for the Products, and shall maintain such global safety database for so long as such Product is under Development and/or Commercialization by the Parties. The Parties will collaboratively agree on data cut points for periodic aggregate safety reports and Exelixis will author such reports; the Parties will jointly review and approve such reports before submission to worldwide Regulatory Authorities as required. Exelixis shall bear one hundred percent (100%) of the cost and expense for establishing and maintaining such global database and the preparation of periodic aggregate safety reports ("**PV Costs**") from the

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Effective Date through [*]. After such date, and subject to Section 4.5(a), Exelixis shall bear [*] percent ([*]%) and Licensee shall bear [*] percent ([*]%) of PV Costs. Exelixis will ensure that each Party and any Future Exelixis Licensee are able to access the data, if necessary indirectly, from the global safety database in order to meet legal and regulatory obligations. The Parties agree that Exelixis shall not transfer the responsibility or holding of the global safety database to any CRO, sublicensee, Future Exelixis Licensee or any Third Party without Licensee's prior written consent and approval, which shall not be unreasonably withheld, conditioned or delayed if such transferee (and its Affiliates) is a pharmaceutical company of comparable size as Licensee and agrees to grant Licensee access and other rights to the global safety database substantially equivalent to those granted by Exelixis under the Pharmacovigilance Agreement. The use by Exelixis of a CRO, sublicensee, Future Exelixis Licensee shall be at Exelixis' sole cost and expenses. 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 Products to the Regulatory Authorities in the Licensee Territory, but each Party shall be primarily responsible for reporting quality complaints, adverse events and Safety Data related to the Products to any Regulatory Authorities and responding to safety issues and to all requests of Regulatory Authorities related to the Products under any MAA or Regulatory Approval for the Product held by such Party and filed with such Regulatory Authorities, in each case at its own cost. 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 may use 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

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obligations, unless the receiving Party pays the other Party for such work pursuant to Section 9.2(c).

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 Licensee shall be governed by the terms and conditions of the Supply Agreement.

5.10 Sunshine Reporting Laws. Each Party acknowledges that the other Party may be subject to federal, state, local and international laws, regulations and rules 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. COMMERCIALIZATIONS

6.1 General. Subject to the terms and conditions of this Article 6 (including Section 6.7), Licensee shall have the sole and exclusive responsibility, at its own expense, for all aspects of the Commercialization of the Products in the Licensee 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. As soon as practical after the Effective Date, Licensee shall prepare and present to the JCC a Commercialization plan for Products in the Licensee

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Territory, including a reasonably detailed description and an anticipated timeline for Licensee's significant Commercialization activities for the Products for the next [*] commencing with the [*] (the "**Commercialization Plan**"). Taking into consideration the requirements of Section 6.3(c), the Commercialization Plan shall include such information on a country-by-country basis for each of the Major Market Countries. Licensee shall update and amend the Commercialization Plan annually starting in November 2017 and each subsequent November, 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, Licensee shall consult with and provide updates to Exelixis ([*]) regarding the commercial strategy and Commercialization of Products in the Licensee Territory. Subject to the provisions of this Agreement and compliance with the Commercialization Plan, Licensee 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, Licensee shall use Commercially Reasonable Efforts to Commercialize the Products for all indications that have received or will receive Regulatory Approval throughout the Licensee Territory. In addition, and without limitation of the foregoing, Licensee shall, as soon as possible following each MAA Approval(s), subject to Section 6.4(b), launch the Product for such indication and obtain all necessary Price and Reimbursement Approvals at least in [*] (subject to the business judgment to delay or not to launch a particular Product in a particular country of the EU because of adverse pricing or other business considerations). In the event that Licensee recommends not to launch a particular Product in a particular country of the Licensee Territory, or to deliberately defer such launch, it shall advise the JCC at the next meeting of such Committee and provide a reasonably detailed rationale for such determination. Thereafter, Licensee shall utilize Commercially Reasonable Efforts in the ongoing support for the Product in each such country. Licensee shall report to the JCC its efforts in each of these countries at least [*] at meetings of the JCC [*].

(b) Additional Markets. Promptly after the Effective Date, Licensee shall commence preparation of a reasonably detailed Commercialization plan, sales forecast, and launch timing for Commercialization of the Product, using Commercially Reasonable Efforts, in the Additional Markets. On or before December 31, 2016, Licensee shall present to the JCC such reasonably detailed Commercialization plan, sales forecast, and launch timing for Commercialization of the Product, using Commercially Reasonable Efforts, in the Additional Markets. Such report shall specifically assess the opportunity and plans for [*].

(c) Minimum Commercial Performance. In addition to the foregoing general commitments, and subject to Section 6.3(e), for each Calendar Year for [*] full Calendar Years commencing [*], Licensee shall prepare a commercially reasonable forecast of commercial sales of Product in the Licensee Territory ("**Sales Forecast**") and submit the Sales Forecast to the JCC with sufficient time for the JCC to review and finalize such Sales Forecast by [*] of the year immediately preceding the year covered in such Sales Forecast. The Sales Forecast shall be based upon the same market share trajectory as the Product achieved in the U.S.

for the same time period following Regulatory Approval (including Pricing and Reimbursement Approval, if required) for each indication, as may be modified on the basis of other relevant commercial considerations, including other comparable product experience in Europe compared to the U.S. For the first [*] Calendar Years following [*], Sales Forecasts will be used solely for management purposes and have no effect under this Agreement. If in any Calendar Year during the remaining [*] Calendar Years (the "**Minimum Commercial Performance Period**") Net Sales realized in the Licensee Territory are less than [*] percent ([*]%) of forecasted sales for such year, then Licensee shall submit a corrective plan to the JCC for review and approval for the next Calendar Year in order to achieve forecasted sales and such corrective plan shall be incorporated into the Commercialization Plan. If, for a second Calendar Year during the Minimum Commercial Performance Period, Net Sales realized are again less than [*] percent ([*]%) of forecasted sales then:

(i) if Licensee failed to execute the corrective plan submitted to the JCC, it shall be considered a material breach giving rise to Exelixis' right to terminate this Agreement pursuant to Section 15.2;

(ii) if Licensee did execute the corrective plan submitted to the JCC, but still failed to achieve at least [*] percent ([*]%) of forecasted sales, then Licensee must submit a new corrective plan to the JCC; and

(iii) if during the Minimum Commercial Performance Period, Licensee fails to achieve at least [*] percent ([*]%) of forecasted sales in [*] of the [*] Calendar Years during the Minimum Commercial Performance Period, it shall be considered a material breach after the [*] of such Calendar Years giving rise to Exelixis' right to terminate this Agreement pursuant to Section 15.2.

(d) Minimum Commercial Performance Compensation. If in any Calendar Year during the Minimum Commercial Performance Period Net Sales realized in the Licensee Territory are less than [*] percent ([*]%) of forecasted sales for such year, then Licensee shall owe to Exelixis the Minimum Commercial Performance Compensation in respect of such year, to be paid within [*] of the end of the relevant Calendar Year. For the purposes of this Agreement, the **"Minimum Commercial Performance Compensation"** shall be equal to the royalty payments due on the difference between [*] percent ([*]%) of the forecasted sales for the applicable Calendar Year and the Net Sales realized during the applicable Calendar Year.

(e) Minimum Commercial Performance Relief. In the event of conditions that give rise to a Stockout Period, Licensee shall be relieved of the obligation to meet minimum commercial performance obligations pursuant to Section 6.3(c) for the Calendar Year in which such Stockout Period occurs.

(f) Commercial Updates. Licensee shall update the JCC on a [*] basis regarding its Commercialization activities with respect to the Products in the Licensee Territory. Each such update shall be in a form to be agreed by the JCC and shall summarize Licensee's, its Affiliates' and Sublicensees' significant Commercialization activities with respect to the Products in the Licensee Territory, and shall contain at least such information at such level of

detail reasonably required by Exelixis to determine Licensee's compliance with its diligence obligations set forth herein. Such updates shall include, on a [*] basis, Licensee's sales activities, marketing activities and Medical Affairs Activities. In addition, if Licensee is then working under a corrective plan under Section 6.3(c), such updates shall also include the budget and actual cost and expense (including FTE levels) for such activities in [*] for the current year and previous year.

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 the Products in both the Licensee Territory and the Exelixis Territory. As such, the Parties, through the JCC, shall develop and coordinate Commercialization strategies for the Product (e.g., for branding and messaging, international congresses, advisory boards), and the Parties shall conduct Commercialization activities for the Product in their respective territories consistent with such global strategy. The foregoing shall not be construed as requiring Exelixis to seek Licensee's consent in connection with the establishment and/or implementation of any sales, marketing, or medical affairs practices in the Exelixis Territory.

(b) Pricing. Licensee 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 Licensee Territory, including any discussion with a Regulatory Authority with respect thereto. Licensee shall have the right to determine the price of the Product sold in the Licensee Territory [*]. [*]. In the event the Pricing and Reimbursement Approvals in a given country of the Licensee Territory is [*], Licensee shall have no obligation to launch the Product in such country. Licensee and its Affiliates and Sublicensees shall not sell any Product in combination with, as part of a bundle with, or as a combination therapy with other products, or offer packaged arrangements to customers that include a Product, in such a manner as to disproportionately discount the selling price of the Product [*]. For clarification, should Licensee derive direct economic benefit from the sale of another pharmaceutical product that is approved to be used in combination with Product, [*].

(c) Sharing of Promotional Materials. Licensee 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 Licensee Territory. The Parties shall share samples of Promotional Materials (including English translation, if available) with respect to 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 request.

(d) Commercialization in Exelixis Territory. Subject to the terms and conditions of this Agreement (including Section 6.7), 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. Licensee shall not engage any contract sales organization to conduct sales activities for the Product in the Licensee Territory without written JCC approval, nor shall Licensee use the same sales force to promote the Product and a separate product that is indicated for the same indication without written JCC approval.

6.6 Medical Affairs Activities.

(a) Coordination of Global Medical Affairs Activities. Commencing with transfer of the RCC MAA to Licensee, but subject to the final sentence of this Section 6.6(a), Licensee shall lead and conduct all Medical Affairs Activities for the Product in the Licensee Territory in accordance with the medical affairs portion of the GDP. From such date, Licensee shall be responsible for Medical Affairs Activities in the Licensee Territory, provided however, that Exelixis shall have the right, but not the obligation, to also conduct Medical Affairs Activities in the Licensee Territory in global support of the Product consistent with the medical affairs portion of the GDP and in coordination with Licensee. Exelixis will not undertake Medical Affairs Activities in the Licensee Territory without prior coordination with Licensee.

(b) Advisory Panels. To the extent practicable, each Party shall give the other Party written notice at least [*] in advance of any major market or international level advisory panel meetings with key opinion leaders with respect to the Commercialization of the Products in the Licensee Territory and the Exelixis Territory that are held, sponsored or attended by either Party or its Affiliate or sublicensee, and each Party shall have the right to attend and participate in 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 will manufacture and supply, itself and/or through a Third Party contract manufacturer, all Compound and Products for use in the Development and Commercialization of the Products under this Agreement. All Products supplied by Exelixis to Licensee shall be at a price equal to [*]. It is anticipated that Exelixis will supply commercial Product to Licensee in either bulk final dosage form or primary

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packaged bulk form as Licensee may specify from time to time. Exelixis shall be responsible for packaging and labeling for all countries in the Licensee Territory until Licensee assumes such responsibilities pursuant to a transition plan, as further described in Section 2.4(e) of the Supply Agreement. The Cost of Goods of the Compound and Products used in the Development work under the GDP shall be included in the Development Cost and shared by the Parties in accordance with Sections 4.5 and 9.2. Exelixis shall source such 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 Licensee is responsible for conducting any Clinical Studies pursuant to Section 4.3, 4.5(d) or 4.5(e), Exelixis shall provide such supply to Licensee for such Clinical Studies in accordance with the GDP. Within two (2) months of the Effective Date, the Parties shall enter into a Supply Agreement for the manufacture and supply of the Compound and Products to Licensee (the "**Supply Agreement**").

8. TRANSITION OF EU REGULATORY AND COMMERCIALIZATION OPERATION.

8.1 Termination of Sobi Agreement. Licensee acknowledges that as of the Effective Date, Exelixis has entered into an Amended and Restated Commercialization Agreement with Swedish Orphan Biovitrum AB ("**Sobi**") for the distribution of the Product in the EU in MTC, effective January 1, 2015 (the "**Sobi Agreement**"). No later than March 4, 2016, Exelixis shall exercise its right to terminate the Sobi Agreement and Exelixis shall bear the cost of any resulting termination payment to Sobi under Section 8.3(g) of the Sobi Agreement. Prior to the effective date of the termination of the Sobi Agreement, Licensee acknowledges and agrees that the licenses granted by Exelixis to Licensee hereunder are subject to the rights granted by Exelixis to Sobi under the Sobi agreement. Exelixis shall ensure that a meeting be held with Sobi and Licensee within sixty (60) days of the Effective Date to achieve a smooth transition from Sobi to Licensee for the distribution of the Product in MTC in the EU. Exelixis agrees, if necessary, to enforce the obligations of the Sobi Agreement as against Sobi to provide for a smooth transition of commercial responsibility for the distribution of the Product in the EU in MTC as contemplated by the Sobi Agreement.

8.2 Transfer of Regulatory Filings. As soon as practicable, but no later than [*], the Parties shall cooperate to transfer the EMA MAA filing from TMC for Cometriq in MTC to Licensee, including Marketing Authorization Holder status (including commitments and obligations listed in the MAA, and Exelixis shall ensure with TMC that such transfer shall occur, except that Exelixis shall complete the EMA post-marketing commitment of Study XL184-401, with the costs of such study to be shared in accordance with Section4.5), and the Pediatric Investigation Plan, provided that Licensee shall be responsible for all Regulatory Filings and interactions with the EMA with respect to such studies and Regulatory Filings, maintaining Orphan Drug Status, and all further EMA requirements with respect to such studies and Regulatory Filings. Without limiting the foregoing, such transfer efforts shall include (a) providing supporting documentation, responding to requests by applicable Regulatory Authorities and other reasonable efforts in connection with the MAA Approvals, (b) preparing and filing Regulatory Filings in countries of the Licensee Territory where Sobi and/or TMC has not as of the Effective Date filed Regulatory Filings and it is or it becomes commercially

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reasonable to do so. Licensee's rights and obligations as a regulatory sponsor with respect to each particular Regulatory Filing under Article 5 shall commence upon the completion of such transfer.

8.3 Transition of Commercial Responsibilities for Cometriq. Licensee and Exelixis acknowledge and agree that Licensee shall assume the rights and responsibilities for the Commercialization of Cometriq in the EU concurrent with the effective date of the termination of the Sobi Agreement. Consistent with Section 8.2, the Parties shall cooperate to effectuate the transfer of such rights and responsibilities to Licensee in a manner that minimizes any delay or interruption of the Commercialization of Cometriq in the EU.

9. FINANCIAL PROVISIONS

9.1 Upfront Payment. Licensee shall make a one-time, non-refundable, non-creditable upfront payment to Exelixis of two hundred million dollars ($200,000,000) within five (5) business days after the Effective Date.

9.2 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 Development activity (other than the Independent Work and Licensee Only Development 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, subject to the other Party's right to audit the invoicing Party's records and books related to such costs as provided in Section 10.4. For clarity, making such a payment does not preempt the paying Party's audit rights under Section 10.4, 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. Except as set forth below in this Section 9.2(c), each Party shall bear all the internal (calculated on an FTE basis using the then current FTE Rate) and out-of-pocket costs and 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

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the other Party a reasonably detailed invoice setting forth [*] percent ([*]%) 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 9.2(b) as if such Independent Work Costs were Development Costs. 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 within [*] after the receipt of such invoice, subject to such Party's right to audit the invoicing Party's records and books related to such costs as provided in Section 10.4. For clarity, making such a payment does not preempt the paying Party's audit rights under Section 10.4, which remain in full force and effect.

(c) Internal Development Cost. Each Party shall record and calculate its internal Development Costs on an FTE basis at the FTE Rate.

(d) Development Cost for Products in Combination. If any Product is Developed under this Agreement in combination with a Party's proprietary product (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 [*] percent ([*]%) of the Development Cost with respect to such Development shall be subject to the Parties' cost sharing under Section 9.2(b) and the Beneficial Party shall be solely responsible for the other [*] percent ([*]%) of the Development Costs.

(e) PV Costs. Commencing [*], no later than [*] after the beginning of each Calendar Quarter, Exelixis shall submit to Licensee a statement setting forth the PV Costs incurred, including Licensee'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, Licensee shall pay the amount invoiced within [*] after the receipt of the invoice, subject to Licensee's right to audit Exelixis records and books related to such costs as provided in Section 10.4. For clarity, making such a payment does not preempt Licensee's audit rights under Section 10.4, which remain in full force and effect.

9.3 Development Milestone Payments.

(a) Development Milestones. Subject to the remainder of this Section 9.3, Licensee 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 Licensee, Exelixis, or their Affiliates, licensee(s) of Exelixis or Sublicensees):

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Milestone Event	Milestone Payments			
	For RCC (2nd line)	For HCC (2nd line)	Tier 1 Additional Indication	Tier 2 Additional Indication
Milestone #1: Initiation of first Phase 3 Clinical Trial	n.a.	n.a.	$20 million	$[*]
Milestone #2: First MAA filing with the EMA	n.a	$10 million	$25 million	$[*]
Milestone #3: First MAA Approval by EMA	$60 million	$40 million	$50 million	$[*]
TOTAL	$60 million	$50 million	$95 million	$[*]

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

(ii) For Tier 1 Additional Indications and Tier 2 Additional Indications, each milestone payment shall be paid once for the applicable milestone events described above for a total payment of [*] for up to [*]. For clarity, such milestone payments may be earned if [*]. In the event that any indication [*].

(iii) 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.

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

(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 9.3 by such Party, its Affiliates or its Sublicensees. Licensee shall pay to Exelixis the applicable development milestone payments within [*] after the delivery or receipt of such notice.

9.4 Commercial Milestones Payments.

(a) EU Launch Milestones. Licensee 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 Licensee, its Affiliates, or Sublicensees):

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EU Launch Milestones	Milestone Payments
First commercial sale of a Product in any country in the Top 5 EU	$10 million
First commercial sale of a Product in any second country in the Top 5 EU	$10 million

(b) Net Sales Milestones. Licensee 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 Licensee 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 Licensee under this Section 9.4 (the "**Previously Achieved Commercial 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 (4^{th}) Calendar Quarter which served as the period to determine the reaching of the Net Sales amount triggering the Previously Achieved Commercial Milestone. For the avoidance of doubt, each payment in this Section 9.4 shall be payable once only, regardless of the number of times such milestone is subsequently achieved.

Aggregate Net Sales of all Products in the Licensee Territory in any 4 consecutive Calendar Quarters	Milestone Payments
Equal or exceed $100 million	$25 million
Equal or exceed $250 million	$50 million
Equal or exceed $[*]	$[*]
Equal or exceed $[*]	$[*]
Equal or exceed $[*]	$[*]

(c) Notice and Payment.

(i) Licensee shall notify Exelixis in writing within [*] after the achievement of any EU launch milestone set forth in Section 9.4(a) above by Licensee, its Affiliates or its Sublicensees. Licensee shall pay to Exelixis the applicable EU launch milestone payments within [*] after the delivery or receipt of such notice.

(ii) As part of the report in Section 10.1, Licensee shall provide written notice to Exelixis if the aggregated Net Sales of all Products in the Licensee Territory in any four (4) consecutive Calendar Quarters first reach the values set forth in Section 9.4(b) above, and Licensee shall pay to Exelixis the corresponding Net Sales milestone payment within [*] after the end of the Calendar Quarter.

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9.5 Royalty Payments.

(a) Royalty Rate. Subject to the other terms of this Section 9.5, during the Royalty Term, Licensee shall make quarterly non-refundable, non-creditable royalty payments to Exelixis on the annual Net Sales of all Products sold in the Licensee Territory at the applicable rate set forth below:

Annual Net Sales of all Products in the Licensee Territory	**Royalty Rate**
Portion less than or equal to $[*]	22%
Portion greater than $[*] and less than or equal to $[*]	[*]%
Portion greater than $[*]	26%

(b) Royalty Term. Royalties shall be paid on a Product-by-Product and country-by-country basis in the Licensee Territory from the First Commercial Sale of such Product in such country by or on behalf of Licensee, its Affiliates or Sublicensees, until the latest of (i) expiration of the lasttoexpire Valid Claim of the Exelixis Patents and Licensee Patents covering such Product in such country, including its composition, method of manufacture or method of use, each covering the Product as Commercialized; (ii) the expiration of any Regulatory Exclusivity covering such Product in such country; or (iii) ten (10) years after the First Commercial Sale of such Product in such country for the first indication to obtain Regulatory Approval in the Licensee Territory other than MTC (the "**Royalty Term**").

(c) Royalty Reductions

(i) If one or more Generic Products to a Product is sold in any country in the Licensee Territory during the Royalty Term for such Product in such country, and [*], the royalty rates provided in Section 9.5(a) for such Product shall be reduced in such country by [*] percent ([*]%) [*].

(ii) If it is [*] for Licensee to obtain a license from a Third Party under any Patent in a particular country in the Licensee Territory in order to sell a Product in such country and Licensee obtains such a license, Licensee may deduct, from the royalty payment that would otherwise have been due pursuant to Section 9.5(a) with respect to Net Sales of such Product in such country in a particular Calendar Quarter, an amount equal to [*] percent ([*]%) of the royalties paid by Licensee to such Third Party pursuant to such license on account of the sale of such Product in such country during such Calendar Quarter.

(iii) If the Applicable Laws (including legal doctrine) in a particular country or jurisdiction requires a royalty reduction after the expiration of the relevant patents, and the Royalty Term for a particular Product in such country or jurisdiction extends beyond the time period set forth in Section 9.5(b)(i), then the royalty rates provided in Section 9.5(a) shall be reduced by [*] percent ([*]%) for such Product in such country (e.g., a reduction from [*]% to [*]%) during the remainder of the Royalty Term that extends beyond the time period set forth

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in Section 9.5(b)(i) unless and until the royalty reduction set forth in Section 9.5(c)(i) becomes applicable. For the same period of time, if neither Exelixis nor Licensee has [*] in such country, such royalty reduction shall be [*] percent ([*]%) instead of [*] percent ([*]%).

(iv) Notwithstanding the foregoing, during any Calendar Quarter in the Royalty Term for a Product in a country, the operation of clause (i), (ii) and (iii) above, individually or in combination, shall not reduce by more than [*] percent ([*]%) the royalties that would otherwise have been due under Section 9.5(a) with respect to Net Sales of such Product in such country during such Calendar Quarter.

(d) Basis of Payment.-This Section 9.5 is intended to provide for royalty payments to Exelixis equal to the percentages of Net Sales set forth in this Section 9.5 for the entire duration of the Royalty Term. In establishing this payment structure, Licensee 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, Licensee 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.

(e) Launch Period Adjustment. For the first fifty million dollars ($50,000,000) of cumulative Net Sales, Licensee shall make quarterly non-refundable, non-creditable royalty payments to Exelixis on the Net Sales of all Products sold in the Licensee Territory at the rate of two percent (2%) rather than at the rate set forth in Section 9.5(a). For the first one hundred million dollars ($100,000,000) of cumulative Net Sales immediately following the initial fifty million dollars ($50,000,000) of cumulative Net Sales, Licensee shall make quarterly non-refundable, non-creditable royalty payments to Exelixis on the Net Sales of all Products sold in the Licensee Territory at the rate of twelve percent (12%) rather than at the rate set forth in Section 9.5(a). Thereafter, the royalty rate for all Net Sales shall be at the applicable rate set forth in Section 9.5(a).

(f) Stockout Holiday. In the event of conditions that give rise to a Stockout Period, Licensee shall be relieved of the obligation to pay royalties pursuant to Section 9.5(a) on Net Sales occurring for a period of time, commencing with the first commercial sale following the end of the Stockout Period, equal in duration to the Stockout Period.

9.6 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 surviving the termination of the Product Development and Commercialization Agreement between [*], as set forth in such Collaboration Agreement.

9.7 Supply Payments. Licensee shall pay Exelixis for Compound and Product Exelixis supplies to Licensee an amount equal to [*], all as provided in the Supply Agreement.

10. PAYMENT; RECORDS; AUDITS

10.1 Payment; Reports. Royalty payments due by Licensee to Exelixis under Section 9.5 shall be calculated and reported for each Calendar Quarter. All royalty payments due under Section 9.5 shall be paid within [*] after the end of each Calendar Quarter and shall be accompanied by a report setting forth, on a country-by-country basis, Net Sales of the Products by Licensee and its Affiliates and Sublicensees in the Licensee Territory in sufficient detail to permit confirmation of the accuracy of the royalty payment made, including, for each country, 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, any adjustments to royalties in accordance with Section 9.5, and whether any commercial milestone under Section 9.4 has been achieved. Promptly after the Effective Date, the Parties will agree on the form of royalty report. Licensee shall submit a single report for all Net Sales during the Calendar Quarter, including all Licensee's, Affiliates' and Sublicensees' Net Sales but shall separately identify the Net Sales and other information applicable to each entity.

10.2 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. When conversion of Net Sales from any currency other than U.S. dollars is required, such conversion shall be at the exchange rate [*]. 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.

10.3 Taxes.

(a) Taxes on Income. 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 or similar obligations in respect of the milestone payments, milestone payments and other payments made by Licensee to Exelixis under this Agreement. To the extent Licensee is required by Applicable Laws to deduct and withhold taxes on any payment to Exelixis, Licensee 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 Licensee any tax forms that may be reasonably necessary in order for Licensee 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 Licensee in advance of the due date. Licensee shall provide Exelixis with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Exelixis. Licensee shall have the right to deduct any such tax, levy or charge actually paid from payment due to Exelixis. Each Party agrees to assist the other Party in claiming exemption from such deductions or

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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 Licensee's Action. Licensee represents and warrants that, as of the Effective Date, Licensee 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. If a Party takes any action of its own discretion (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 ("**Withholding Tax Action**"), then such Party shall pay the sum associated with such Withholding Tax Action. For clarity, if Licensee undertakes a Withholding Tax Action, then the sum payable by Licensee (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 which it would have received had no such Withholding Tax Action occurred. Otherwise, the sum payable by Licensee (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 Licensee to the applicable Governmental Authority on behalf of Exelixis, provided that Licensee shall assist Exelixis in minimizing or recovering such withholding or deduction obligation. 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.

10.4 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, the amount of royalty and other payments under this Agreement. Each Party will keep such books and records for at least [*] following the Calendar Year to which they pertain. 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 may occur no more often than once each Calendar Year and not more frequently than once with respect to records covering any specific period of time. Each Party shall only be entitled to audit the books and records from the [*] Calendar Years prior to the Calendar Year in which the audit request is made. 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

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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 overpayment to, or an underpayment by, the audited Party that resulted from a discrepancy in the financial report provided by the audited Party for the audited period, which underpayment or overpayment was more than [*] percent ([*]%) of the amount set forth in such report, in which case the audited Party shall reimburse the auditing Party for the costs for such audit. With respect more specifically to the Development Costs to be paid or shared pursuant to Section 9.2, in addition to the right of inspection and audit by an Auditor, the Party making the payment (the "**Payor**") shall have the right at its expense to review any records of out-of-pocket costs and expenses incurred by the Party requesting the payment (the "**Payee**") and time-keeping logs of Payee sufficient to justify the work-time spent by each FTE of the Payee as well as the books of the Payee upon reasonable notice sent by Payor to Payee and during regular business hours. For clarity, making such a payment does not preempt the paying Party's audit rights under this Section 10.4, which remain in full force and effect. Payee's FTE's work-time shall be appropriately allocated between the other product and the Product for purpose of calculating the internal costs specifically dedicated to the Product.

10.5 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 the [*] interest rate of [*] percent ([*]%) [*]; 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.

11. INTELLECTUAL PROPERTY

11.1 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 Licensee) (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 Licensee or its Affiliates or Sublicensees (the "**Licensee Data**") shall be the sole and exclusive property of Licensee or of its Affiliates or Sublicensees, as applicable. For clarity, each Party shall have access and 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 (each, a "**Compound Invention**"). All Compound Inventions will be included in the Exelixis Know-How, and Patents in the Licensee Territory claiming such Inventions will be included in the Exelixis Patents. To the extent any Compound Invention is made by Licensee, whether solely or jointly with Exelixis, Licensee shall, and hereby does, transfer and assign to Exelixis, without additional consideration, all of its interest in such Compound Invention.

(ii) Except for Compound Inventions, each Party shall solely own any Inventions made solely by its and its Affiliates' employees, agents, or independent contractors ("**Sole Inventions**"), and the Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of one Party and its Affiliates together with employees, agents, or independent contractors of the other Party and its Affiliates ("**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.

11.2 Patent Prosecution and Maintenance.

(a) Exelixis Patents.

(i) Subject to this Section 11.2(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 Licensee Territory. Licensee shall reimburse Exelixis for all costs and expenses incurred with respect to the preparation, filing, prosecution and maintenance of Exelixis Patents in the Licensee Territory after the Effective Date, within [*] from the date of invoice for such costs and expenses provided by Exelixis. In the event that Licensee 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 Licensee under this Agreement. Exelixis shall keep Licensee informed of material progress with regard to the preparation, filing, prosecution and maintenance of Exelixis Patents in the Licensee Territory, sufficiently in advance for Licensee to be able to review any material documents, including content, timing and jurisdiction of the filing of such Exelixis Patents in the Licensee Territory, and Exelixis shall consult with, and consider in good faith the requests and suggestions of, Licensee with respect to strategies for filing, prosecuting and defending, if any, Exelixis Patents in the Licensee Territory.

(ii) In the event that Exelixis desires to abandon or cease prosecution or maintenance of any Exelixis Patent in any country in the Licensee Territory, Exelixis shall

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provide reasonable prior written notice to Licensee 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 Licensee's written election provided no later than [*] after such notice from Exelixis, Exelixis shall continue prosecution and maintenance of such Exelixis Patent at Licensee's direction and expense. If Licensee 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) Licensee Patents.

(i) Subject to this Section 11.2(b), Licensee 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 Licensee Patents (other than Joint Patents) worldwide, at its sole cost and expense and by counsel of its own choice in the Licensee Territory and by counsel mutually agreed to by the Parties in the Exelixis Territory. Licensee shall keep Exelixis informed of the status of filing, prosecution, maintenance and defense, if any, of the Licensee Patents, and Licensee 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, Licensee Patents.

(ii) In the event that Licensee desires to abandon or cease prosecution or maintenance of any Licensee Patent, Licensee 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 Licensee Patent in the relevant patent office). In such case, upon Exelixis' written election provided no later than [*] after such notice from Licensee, Exelixis shall have the right to assume prosecution and maintenance of such Licensee Patent at Exelixis' expense and Licensee shall assign to Exelixis all of its rights, title and interest in and to such Licensee Patent. If Exelixis does not provide such election within [*] after such notice from Licensee, Licensee may, in its sole discretion, continue prosecution and maintenance of such Licensee Patent or discontinue prosecution and maintenance of such Licensee Patent.

(c) Joint Patents.

(i) Subject to this Section 11.2(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 Licensee Territory. Licensee shall reimburse Exelixis for all costs and expenses incurred with respect to the preparation, filing, prosecution and maintenance of Joint Patents in the Licensee Territory, within

[*] from the date of invoice for such costs and expenses provided by Exelixis. In the event that Licensee 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, Licensee shall execute such documents and perform such acts, at Licensee's expense, as may be reasonably necessary to effect an assignment of Licensee'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 a Exelixis Patent and shall no longer be subject to the licenses and other rights granted by Exelixis to Licensee under this Agreement. Exelixis shall keep Licensee 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, Licensee with respect to filing, prosecuting and defending, if any, Joint Patents in the Licensee Territory.

(ii) In the event that Exelixis desires to abandon or cease prosecution or maintenance of any Joint Patent in any country in the Licensee Territory, Exelixis shall provide reasonable prior written notice to Licensee 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 Licensee's sole discretion, upon written notice from Licensee to Exelixis, Licensee 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 Licensee's expense, as may be reasonably necessary to allow Licensee to continue the prosecution and maintenance of such Joint Patent in such country in the Licensee Territory. Any such assignment shall be completed in a timely manner to allow Licensee 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 Licensee Patent and shall no longer be subject to the licenses and other rights granted by Licensee 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 11.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates and their equivalent with respect thereto respectively, at its own cost (except as expressly set forth otherwise in this Article 11). Such cooperation includes: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by Section 11.2; 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.

11.3 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 Licensee Territory, which infringement adversely affects or is

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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 Licensee promptly) or (ii) Exelixis otherwise fails to bring such legal action against a Product Infringement within [*] of first becoming aware of such Product Infringement, Licensee 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, shall reasonably consider the other Party's comments on any such efforts, including, without limitation, determination of litigation strategy, 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 cost and 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 Licensee Territory, Licensee shall have the option to share [*] percent ([*]%) of the cost and expense incurred by Exelixis in such enforcement action, which option may be exercised by Licensee by providing written notice to Exelixis within [*] after receiving a notice from Exelixis that Exelixis decides to bring such action. If Licensee exercises such option, then (1) Licensee shall reimburse Exelixis for [*] percent ([*]%) of all costs and expenses incurred by Exelixis in such enforcement action, within [*] from the date of invoice for such costs and expenses provided by Exelixis; (2) If Exelixis recovers any monetary damages in such enforcement action, such recovery shall be allocated [*] percent ([*]%) to Exelixis and [*] percent ([*]%) to Licensee.

(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

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anywhere in the world. For clarity, Exelixis shall have the exclusive right to enforce (i) the Exelixis Patents against any infringement in the Licensee 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 Licensee Patents, including the defense of validity and enforceability challenges arising from any enforcement action.

11.4 Infringement of Third Party Rights. If any Product used or sold by Licensee, 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 Licensee Territory, Licensee 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 defend itself from any such Third Party claim at its own cost and expense, provided, however, that the provisions of Section 11.3 shall govern the right of Licensee to assert a counterclaim of infringement of any Exelixis Patents.

11.5 Patents Licensed From Third Parties. Each Party's rights under this Article 11 with respect to the prosecution and enforcement of any Exelixis Patent and Licensee 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.

11.6 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. The Parties (including any Future Exelixis Licensee to the extent feasible) shall collaborate to have a global, worldwide trademark to be used on the Product. The Parties acknowledge that Exelixis has been using the trademark Cometriq® for the Product in MTC, and unless otherwise mutually agreed, the Parties shall continue to use Cometriq® in MTC. Exelixis shall select another Product Mark for the Product to be used for all other indications. In the event Exelixis is unable to obtain or maintain the Product Marks for the Product in the Licensee Territory or in some countries in the Licensee Territory, the Parties shall collaborate to select such other Product Marks (*i.e.*, back-up names) as may be available for registration and marketing of the Product in those countries. 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 Licensee Territory. Licensee shall reimburse Exelixis for all costs and expenses incurred with respect to the registration and maintenance of the Product Marks in the Licensee Territory, within [*] from the date of invoice for such costs and expenses provided by Exelixis.

Exelixis shall keep Licensee informed of material progress with regard to the registration, prosecution, maintenance and defense, if any, of Exelixis Trademarks in the Licensee Territory, including content, timing and jurisdiction of the filing of such Exelixis Trademarks in the Licensee Territory, sufficiently in advance for Licensee to be able to review any material documents, and Exelixis shall consult with, and consider in good faith the requests and suggestions of, Licensee with respect to strategies for filing, prosecuting and defending, if any, Exelixis Trademarks in the Licensee Territory.

(b) Trademark License. Licensee shall use the Product Marks selected by Exelixis to Commercialize the Product in the Licensee Territory. Where Licensee reasonably believes the Product Mark is not appropriate for commercial use in a specific country, the Parties shall agree on an alternative product trademark for such country and such alternative product trademark shall be included in Product Mark. In addition, unless prohibited by Applicable Laws, Licensee shall use Commercially Reasonable Effort to include Exelixis' corporate trademark on the packaging and product information (i.e. SmPC) of the Products sold in the Licensee Territory to indicate that the Product is licensed from Exelixis. Exelixis hereby grants to Licensee 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 Licensee Territory 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, Licensee shall also include its (or its Affiliate's or Sublicensee's) corporate logo in the Product sold in the Licensee Territory.

12. REPRESENTATIONS AND WARRANTIES

12.1 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.

12.2 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.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(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. Licensee covenants as follows:

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

(ii) Licensee 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, Licensee (and Licensee represents and warrants that as of the Effective Date, Licensee, 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 Entity or any other person in connection with the performance of Licensee's obligations under this Agreement, and Licensee covenants that it and its Affiliates' employees and contractors shall not, directly or indirectly, engage in any of the foregoing).

(iii) Licensee 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, rules or regulations or otherwise cause any reputational harm to Exelixis.

(iv) Licensee shall immediately notify Exelixis if Licensee has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any other Applicable Laws, rules or regulations 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, Licensee shall comply and shall cause its and its Affiliates' employees and contractors to comply with Licensee's own anti-corruption and anti-bribery policy, a copy of which has been provided to Exelixis prior to the Effective Date.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(vi) Exelixis will have the right, upon reasonable prior written notice and during Licensee's regular business hours, to conduct at its own cost and expenses inspections of and to audit Licensee's books and records in the event of a suspected violation or to ensure compliance with the representations, warranties or covenants of this Section 12.2(c); provided, however, that in the absence of good cause for such inspections and audits, Exelixis exercise this right no more than annually.

(vii) In the event that Licensee has violated or been suspected of violating any of the representations, warranties, or covenants in this Section 12.2(c), Licensee will cause its or its Affiliates' personnel or others working under its direction or control to submit to periodic training that Licensee will provide on anti-corruption law compliance.

(viii) Licensee will, at Exelixis' request, annually certify to Exelixis in writing Licensee's compliance, in connection with the performance of Licensee's obligations under this Agreement, with the representations, warranties, or covenants in Section 12.2(c), which certification shall be issued by Licensee's global commercial head for the Product.

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

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

(a) **Exhibit B** lists all Patents Controlled by Exelixis in the Licensee Territory as of the Effective Date that claim the composition of matter or use of the Compound and have been filed, prosecuted and maintained in a manner consistent with Exelixis' standard practice, in each applicable jurisdiction in which such Patent have been filed, that no official final deadlines with respect to prosecution thereof have been missed and all applicable fees have been paid on or before the due date for payment;

(b) All inventors of Inventions claimed in the Patent listed on **Exhibit B** have assigned their entire right, title and interest in and to such inventions to Exelixis and the inventors listed are correct and there are no claims or assertions in writing received by Exelixis regarding the inventorship of such Patent alleging that additional or alternative Inventors ought to be listed;

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

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

(e) 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;

(f) 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 Licensee hereunder;

(g) 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 [*];

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

(i) Exelixis has disclosed to Licensee all clinical and non-clinical data in the Control of Exelixis that is material to the evaluation of the safety, efficacy and manufacturing process of the Product; and

(j) 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 Licensee in the course of Licensee's due diligence.

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

12.5 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 pursuant to this Agreement or the safety or usefulness for any purpose of the technology it provides hereunder.

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13. INDEMNIFICATION

13.1 Indemnification by Exelixis. Exelixis hereby agrees to defend, indemnify and hold harmless Licensee and its Affiliates and their respective directors, officers, employees and agents (each, an "**Licensee Indemnitee**") from and against any and all liabilities, expenses and losses including any product liability, personal injury, property damage, including reasonable legal expenses and attorneys' fees (collectively, "**Losses**"), to which any Licensee 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 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 Licensee or its Affiliates or Sublicensees), (b) the gross 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 Section 13.2(a), (b) or (c) for which Licensee is obligated to indemnify the Exelixis Indemnitee under Section 13.2.

13.2 Indemnification by Licensee. Licensee hereby agrees to defend, indemnify and hold harmless Exelixis, its Affiliates and licensees and their respective directors, officers, employees and agents (each, a "**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 Development, use, handling, storage, Commercialization or other disposition of any Compound or Product by Licensee or its Affiliates or Sublicensees or the contractor of any of them, (b) the gross negligence or willful misconduct of any Licensee Indemnitee, or (c) the breach by Licensee of any warranty, representation, covenant or agreement made by Licensee in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of any activities set forth in Section 13.1(a), (b) or (c) for which Exelixis is obligated to indemnify the Licensee Indemnitee under Section 13.1.

13.3 Procedure. A party that intends to claim indemnification under this Article 13 (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 in the Indemnitor's defense of and settlement negotiations for any Claim with counsel of the Indemnitee's own selection. The indemnity arrangement in this Article 13 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 withheld or delayed unreasonably. 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 13 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.

13.4 Insurance. Each Party, at its own expense, for a period until [*] after expiration or termination of this Agreement, shall maintain commercial general liability insurance, including public and product liability and other appropriate insurance (e.g., contractual liability, bodily injury, property damage and personal injury coverage) (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term, at a minimum equivalent to [*] dollars ($[*]) for any one claim or in the aggregate. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request. It is understood that such insurance shall not be construed to create any limit of either Party's obligations or liabilities with respect to its indemnification obligations hereunder. In the event of use by either Party of subcontractors, Sublicensees or any Third Party in the performance of such Party's obligations under the Agreement, such Party shall ensure that its subcontractor, Sublicensee or Third Party shall have a proper and adequate general liability insurance to cover its risks with respect to the other Party for damages mentioned above.

13.5 Limitation of Liability. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 14, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided, however, that this Section 13.5 shall not be construed to limit either Party's indemnification obligations under this Article 13.

14. CONFIDENTIALITY

14.1 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 14.2 and 14.3 and 14.5, 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 (but no less than reasonable care) to ensure that its 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.

14.2 Exceptions. The obligations of confidentiality and restriction on use under Section 14.1 will not apply to any information that the receiving Party can prove by competent written evidence: (a) is now, 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 at the time of receiving such information, other than by previous disclosure of the

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disclosing Party, or its Affiliates, employees, agents, consultants, or contractors; (c) is hereafter furnished to the receiving Party 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 the receiving Party without the use of Confidential Information belonging to the disclosing Party.

14.3 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) 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 court orders or governmental regulations; and

(e) disclosure to its and its Affiliates' 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 and 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; and

(f) 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, *provided that* the disclosing Party redacts the financial terms and other provisions of this Agreement that are not reasonably required to be disclosed in connection with such potential investment, acquisition or collaboration, which redaction shall be prepared in consultation with the other Party.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 14.3(c) or (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 14.3(c) or (d) shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 14.

14.4 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 [*], whether by oral presentation, manuscript or abstract. Before any such material is submitted for publication, or presentation of any such material is made, each Party shall deliver a complete copy of the material proposed for disclosure to the other Party at least three (3) weeks (for oral presentations or abstracts) or five (5) weeks (for manuscripts) prior to submitting the material to a publisher or initiating any other disclosure. Each Party shall review any such material and give its comments to the other Party within two (2) weeks (for oral presentations or abstracts) or twenty (20) days (for manuscripts) of the receipt of such material. With respect to oral presentation materials and abstracts, each Party shall make reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to the other Party with appropriate comments, if any. Each Party shall comply with the other Party's request to delete references to its Confidential Information in any such material and agrees to not make any submission for publication or other public disclosure in order not to jeopardize the patentability of any results or data for the purpose of preparing and filing appropriate patent applications as provided in Section 14.4(b).

(b) If the non-Publishing Party notifies the Publishing Party that such publication or presentation, in the non-Publishing Party's reasonable judgment, (i) contains an invention for which such Party desires to obtain patent protection, (ii) contains any Confidential Information of such Party, or (iii) could be expected to have an adverse effect on the commercial value of any Confidential Information disclosed by such Party to the Publishing Party, the Publishing Party shall delete such Confidential Information from the proposed publication or presentation.

(c) For as long as the JDC or JCC remains in place, the JDC or JCC shall be responsible for overseeing and facilitating the Parties' communications and activities with respect to publications and presentations under this Section, and for serving as the initial forum for resolving any disputes between the Parties arising under this Section.

14.5 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 E announcing the signature of this Agreement at or shortly after the Effective Date within the time-period as required by relevant 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

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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.

14.6 Prior Confidentiality Agreement. As of the Effective Date, the terms of this Article 14 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) relating to the subject of this Agreement, including the Confidentiality Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

14.7 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 14. 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 14.

15. TERM AND TERMINATION

15.1 Term.

(a) This Agreement shall commence on the Effective Date and, unless terminated earlier as provided in this Article 15 or by mutual written agreement of the Parties, shall continue until the expiration of the last Royalty Term in the Licensee Territory (the "**Term**").

(b) Notwithstanding anything herein, on a Product-by-Product and country-by-country basis, upon the expiration of the Royalty Term (*i.e.*, all royalty payment obligations for a Product in a country), the licenses granted to Licensee in Section 2.1 shall be deemed to be perpetual and fully paid-up with respect to such Product in such country, but thereafter shall be on a non-exclusive basis.

15.2 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 15.2 unless and until an arbitral panel, in accordance with Article 16, 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

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an arbitration alleging material breach by Licensee and Licensee later delivers notice of voluntary termination under Section 15.3(b), then, at the election of Exelixis, the period of time set forth in Section 15.3(b) 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 Licensee if Licensee 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. Licensee 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 EMA.

15.3 Termination without Cause.

(a) Termination in Its Entirety by Licensee. Licensee shall have the right to terminate this Agreement in its entirety, or for only the countries that are under the EMA jurisdiction, without cause upon [*] prior written notice to Exelixis if the EMA refuses to approve the MAA for the Product in Renal Cell Carcinoma (2nd line therapy). For the purpose of this Section 15.3(a), if EMA conditions such MAA Approval on the performance of additional

Phase 3b or other studies, then EMA shall not be deemed to have refused the approval of such MAA.

(b) Termination by Region by Licensee. Licensee shall have the right to terminate this Agreement on a Region-by-Region basis without cause upon [*] prior written notice to Exelixis following the First Commercial RCC Sale of any Product in a given Region; provided however that Licensee may not provide such notice of termination of this Agreement in a Region prior to the [*] anniversary of the First Commercial RCC Sale of any Product (other than Cometriq) in such Region. In the event that termination occurs for the EU, then termination shall automatically be considered to have occurred for the entire Licensee Territory.

15.4 Effects of Termination. Upon any termination of this Agreement by either Party, the following will apply: If this Agreement is terminated only with respect to a particular Region, then the following shall apply to the terminated Region and the terminated Region shall be included in Exelixis Territory. 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 Licensee will automatically terminate, including all sublicenses granted by Licensee to any Sublicensee. Except in the event of termination by Licensee under Section 15.2(a) for material breach by Exelixis, the licenses granted by Licensee to Exelixis shall survive such termination and shall automatically become worldwide or for the terminated Region if the Agreement is terminated only for a particular Region.

(b) Regulatory Materials; Data. Except in the event of termination by Licensee under Section 15.2(a) for material breach by Exelixis, within [*] of the effective date of such termination, Licensee 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 Licensee, its Affiliates or Sublicensees on the Product and all pharmacovigilance data (including all adverse event database) on the Products. In addition, at Exelixis' request, Licensee shall provide Exelixis with reasonable assistance with any inquiries and correspondence with Regulatory Authorities regarding the Product in the Licensee Territory, such assistance shall be limited to a period of [*] after such termination and not to exceed a total of [*] of working time without charge (with any additional time to be charged at the FTE Rate). The transfer and assignment under this Section 15.4(b) shall apply with respect to the terminated Region if the Agreement is terminated only for a particular Region.

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

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(d) Cost of Ongoing Trials. If there is any ongoing Clinical Trial of the Product under the GDP for which the Parties are sharing cost, then Licensee shall continue to share the cost of such Clinical Trial until the effective date of termination. The remaining costs from the effective date of termination until completion of such Clinical Trial (or early termination of such Clinical Trial by Exelixis) shall be either (i) borne entirely by Exelixis following the effective date of termination if termination occurs as a result of Exelixis' breach, or (ii) shared by Licensee for the duration of such Clinical Trial if termination occurs as a result of Licensee's breach, or pursuant to Section 15.3 or Section 2.8(c)(i).

(e) Commercial Wind-Down. Licensee shall, as directed by Exelixis, (i) continue certain ongoing Commercial activities of Licensee and its Affiliates and Sublicensees with respect to any Product in the Licensee 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, the Licensee shall continue to book sales and pay royalties to Exelixis. Except as necessary to conduct the foregoing activities as directed by Exelixis, Licensee 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, Licensee shall immediately deliver to Exelixis (at Licensee's expense) all samples, demonstration equipment, sales materials, catalogs, and literature of Exelixis in Licensee's possession or control.

(f) Transition Assistance. Licensee 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. Except for termination by Licensee under Section 15.2, Exelixis may, in its sole discretion, postpone the effective date of any termination for a period of up to [*]. Except in the event of termination by Licensee under Section 15.2(a) for material breach by Exelixis, Licensee shall, at no cost to Exelixis, provide reasonable consultation and assistance for a period of no more than [*] after termination (and in any case not to exceed a total of [*] of working time including the assistance provided under Section 15.4(b)) for the purpose of transferring or transitioning to Exelixis all Licensee Know-How not already in Exelixis' possession and, at Exelixis' request, all then-existing commercial arrangements relating to the Products that Licensee is able, using Commercially Reasonable Efforts, to transfer or transition to Exelixis or its designee, in each case, to the extent reasonably necessary or for Exelixis to continue the Development and/or Commercialization of the Compound and Products in the Licensee Territory. If any such contract between Licensee 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 for Exelixis to continue the Development and/or Commercialization of the Compound and Products in the Licensee Territory, or if Licensee is performing such work for the Compound and Product itself (and thus there is no contract to assign), then Licensee shall reasonably cooperate with Exelixis to negotiate for the continuation of such services for Exelixis from such entity, or Licensee 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.

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

(h) Non-Compete. Following any termination of this Agreement by Licensee pursuant to Section 2.8(c)(i) or Section 15.3, or by Exelixis pursuant to Section 15.2, neither Licensee nor any of its Affiliates shall (directly or indirectly, either with or without a bona fide collaborator or any other Third Party) commercialize any Competing Product for either (i) a period of [*] (in case of termination pursuant to Section 2.8(c)(i)) or [*] (in case of termination by Licensee pursuant to Section 15.3 or Exelixis pursuant to Section 15.2) following the effective date of such termination, or (ii) [*], whichever is shorter.

15.5 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 such Party may keep one copy of such materials for archival purposes only subject to continuing confidentiality obligations. All Licensee Data and Regulatory Filings assigned to Exelixis upon termination of this Agreement will be deemed Exelixis' Confidential Information and no longer Licensee's Confidential Information.

15.6 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: Article 1 (Definitions); Article 10 (Payments, Records, Audits); Article 13 (Indemnification); Article 15 (Dispute Resolution); Article 17 (General Provisions); Section 5.10 (Sunshine Reporting Laws); Section 11.1 (IP Ownership); Sections 14.1, 14.2, 14.3, 14.6, 14.7 (Confidentiality); and Section 15.4 (Effects of Termination).

15.7 Exercise of Right to Terminate. All rights and obligations of a Party accrued prior to the effective date of a termination (including the rights to receive reimbursement for costs incurred prior to the effective date of such termination and payments accrued or due prior to the effective date of such termination) shall survive such termination.

15.8 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and will otherwise 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

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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.

16. DISPUTE RESOLUTION

16.1 Objective. The Parties recognize that disputes as to matters arising under 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 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 16 to resolve any such dispute if and when it arises.

16.2 Executive Mediation. The Parties will try to settle any dispute, controversy or claim that arises out of, or relates to, any provision of the Agreement ("**Disputed Matter**") by first referring the Disputed Matter to the CEO of Exelixis (or his designee) and the CEO of Licensee (or his designee). 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, such CEOs (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 such CEOs (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 16.3 below.

16.3 Dispute Resolution.

(a) If the Parties are unable to resolve a Disputed Matter using the process described in Section 16.2, 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 London, the United Kingdom, 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. The Parties hereby agree to engage

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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 [*]. The Parties further agree to the ability, right, and power to subpoena Third Party witnesses for both discovery and hearing purposes. The discovery provided for herein may commence once the Terms of Reference have been signed by the Parties and the panel of arbitrators. The panel of arbitrators shall address the time required for the completion of discovery at the initial case management conference and shall address any discovery issues if any arise based on motion and arbitral order. After conducting any hearing and taking any evidence deemed appropriate for consideration, the arbitrators will be requested to render their opinion within [*] of the final arbitration hearing. No panel of arbitrators will have the power to award damages excluded pursuant to Section 13.5 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 16.3 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 bear or pay one-half of those costs and fees and the arbitrators' award will so provide. Notwithstanding the foregoing, each Party is to bear or pay 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 16.2 or 16.3(a), 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 14) 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 in accordance with by the ICC pursuant to its ICC emergency arbitration procedures then in effect and applying the substantive law specified in Section 16.2. 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 16.2 and 16.3(a).

(c) Notwithstanding the foregoing, this Section 16.3 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.

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17. GENERAL PROVISIONS

17.1 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 New York, United States, without reference to its conflicts of law principles.

17.2 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.

17.3 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.

17.4 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

17.5 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.

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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 17.5. Any assignment not in accordance with this Section 17.5 shall be null and void.

17.6 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, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

17.7 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by (a) air mail (postage prepaid) requiring return receipt, (b) overnight courier, or (c) 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 17.7. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of actual receipt; (ii) if air mailed, five (5) days after the date of postmark; (iii) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries or (iv) 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 Licensee, notices must be addressed to:

Ipsen Pharma SAS
65 quai Georges Gorse
92100 Boulogne-Billancourt
France
Attention: Executive VP, General Counsel
Facsimile: [*]

If to Exelixis, notices must be addressed to:

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

17.8 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 (the "**Standstill Period**"), neither Licensee nor any of its Affiliates, without the prior consent of Exelixis or except as

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provided for in this Agreement or in any agreement referred to herein, or in any agreement executed after the Effective Date by Exelixis with Licensee 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, Licensee and its Affiliates then own more than five percent (5%) 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 a 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 a 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 a Exelixis Entity;

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

(iv) take any action that might require a Exelixis Entity to make a public announcement regarding any of the types of matters set forth in clause "(i)" of this Section 17.8(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 17.8(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 17.8(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.

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(b) Notwithstanding the foregoing provisions, Licensee or its Affiliates will not be subject to any of the restrictions set forth in this Section 17.8 with respect to a 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 thirty five percent (35%) of the voting securities or equity interest in such Exelixis Entity; or

(v) if a Third Party makes a public announcement of a bone 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 Licensee 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 acquisition of beneficial ownership of any securities or any assets of any Exelixis Entity, including discussing a right of first refusal before a Exelixis Entity intends to pursue any Acquisition Transaction; or (ii) proposing other collaborative research agreements or other commercial license agreements to Exelixis.

(d) the Parties agree to discuss whether to terminate the Standstill Period on a biennial basis at the anniversary date of the Effective Date.

17.9 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, 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 raw materials, or any other event similar

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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.

17.10 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.

17.11 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}

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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.	**IPSEN PHARMA S.A.S**
By: /s/ Michael M. Morrissey	By: /s/ Marc de Garidel
Name: Michael M. Morrissey	Name: Marc de Garidel
Title: CEO	Title: Chairman & CEO

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List of Exhibits:

Exhibit A: Chemical Structure of cabozantinib

Exhibit B: Exelixis Patents

Exhibit C: Approved Distributors

Exhibit D: Initial Global Development Plan and Budget

Exhibit E: Press Release

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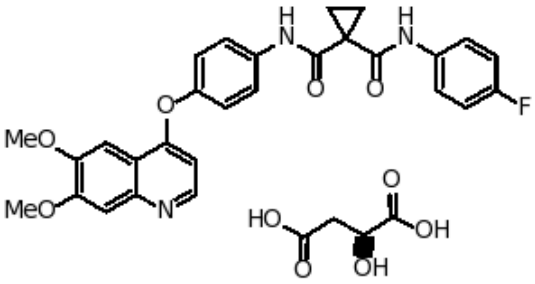
Exhibit A

CHEMICAL STRUCTURE OF CABOZANTINIB



Cabozantinib (*S*)-malate salt

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Exhibit B

LIST OF EXELIXIS PATENTS

{redacted Exhibit B content comprises approximately 23 pages}
[*]

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Exhibit C
APPROVED DISTRIBUTORS
[*]

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Exhibit D

GLOBAL DEVELOPMENT PLAN

{redacted Exhibit D content comprises 2 pages}

[*]

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Exhibit E

PRESS RELEASE

EXELIXIS
www.exelixis.com
210 East Grand Ave
South San Francisco, CA 94080
650.837.7000 main
650.837.8205 fax

IPSEN
Innovation for patient care

Exelixis Contacts

Financial Community:
Susan Hubbard
Investor Relations and
Corporate Communications
(650) 837-8194
shubbard@exelixis.com

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

Ipsen Contacts

Media:
Didier Véron
Senior Vice-Président, Public Affairs and Communication
Tel.: +33 (0)1 58 33 51 16
Fax: +33 (0)1 58 33 50 58
E-mail: didier.veron@ipsen.com

Financial Community:
Stéphane Durant des Aulnois
Vice President, Investor Relations
Tel.: +33 (0)1 58 33 60 09
Fax: +33 (0)1 58 33 50 63
E-mail: stephane.durant.des.aulnois@ipsen.com

EXELIXIS AND IPSEN ENTER INTO EXCLUSIVE LICENSING AGREEMENT TO COMMERCIALIZE AND DEVELOP NOVEL CANCER THERAPY CABOZANTINIB IN REGIONS OUTSIDE THE UNITED STATES, CANADA AND JAPAN

- Cabozantinib commercialized for medullary thyroid cancer (MTC) and filed for advanced renal cell carcinoma (RCC) -
- $200 million upfront payment and subsequent regulatory and commercial milestones -

South San Francisco, Calif. and Paris, France – February 29, 2016 – Exelixis, Inc. (NASDAQ:EXEL) and Ipsen (Euronext: IPN; ADR: IPSEY) today jointly announced an exclusive licensing agreement for the commercialization and further development of cabozantinib, Exelixis' lead oncology drug. Under the agreement, Ipsen will have exclusive commercialization rights for current and potential future cabozantinib indications outside of the United States, Canada and Japan. This agreement includes rights to COMETRIQ®, which is currently approved in the European Union (EU) for the treatment of adult patients with progressive, unresectable, locally advanced or metastatic medullary thyroid cancer (MTC). The companies have agreed to collaborate on the development of cabozantinib for current and potential future indications. Exelixis will maintain exclusive commercial rights for cabozantinib in the United States and Canada, and continue its discussions to partner commercial rights in Japan.

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Under the agreement, Exelixis will receive a $200 million upfront payment. Exelixis is eligible to receive regulatory milestones, including $60 million upon the approval of cabozantinib in Europe for advanced renal cell carcinoma (RCC) and $50 million upon the filing and approval of cabozantinib in Europe for advanced hepatocellular carcinoma (HCC), as well as additional regulatory milestones for potential further indications. The agreement also includes up to $545 million of potential commercial milestones and provides for Exelixis to receive tiered royalties up to 26% on Ipsen's net sales of cabozantinib in its territories.

Marc de Garidel, Chairman and Chief Executive Officer of Ipsen said: "The robust results from the METEOR study in advanced renal cell carcinoma demonstrate that cabozantinib has the potential to become a key oncology product in Europe. This transaction will help Ipsen accelerate the growth of the company and strengthen its oncology footprint in Europe. We are excited to bring cabozantinib to patients and clinicians around the world."

Future commercial indications for cabozantinib could include advanced HCC, the subject of CELESTIAL, an Exelixis-sponsored phase 3 pivotal trial for which top-line 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 (NCI-CTEP), and its ongoing Investigator-Sponsored Trial (IST) 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.

"In Ipsen, Exelixis has an ideal partner to maximize the potential for cabozantinib to have a positive impact on the treatment of cancer on a global basis," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Ipsen's established international oncology marketing presence, late-stage clinical development expertise and shared vision with Exelixis for the franchise potential of cabozantinib will accelerate cabozantinib's commercialization in its territories, while Exelixis remains focused on our launch in the United States. While our immediate priority will be on advanced renal cell carcinoma, Exelixis and Ipsen are committed to exploring and potentially developing cabozantinib in a variety of cancer settings."

Cabozantinib is a small molecule therapy that inhibits the activity of tyrosine kinases including VEGF receptors, MET, AXL, and RET. Following positive results from the METEOR global phase 3 pivotal trial, the tablet form of cabozantinib is the subject of pending U.S. and EU regulatory applications for use as a treatment for advanced RCC in patients who have received one prior therapy. In the EU, the Marketing Authorization Application (MAA) for cabozantinib in advanced RCC has been accepted and granted accelerated assessment. With this designation, the MAA is eligible for a 150-day review, versus the standard 210 days (excluding clock stops when information is requested by the EMA). Exelixis plans to transfer sponsorship of this MAA to Ipsen. Exelixis also anticipates transitioning the commercialization rights to COMETRIQ® outside the U.S. from Exelixis' current international partner for COMETRIQ®, Swedish Orphan Biovitrum AB (Sobi), to Ipsen, in accordance with the terms of its agreement with Sobi. In March 2014, the capsule form of cabozantinib was approved by the European Commission under the trade name COMETRIQ for the treatment of patients with progressive, unresectable, locally advanced or metastatic MTC.

About the METEOR Phase 3 Clinical Trial
METEOR is a global, randomized open-label trial that compares cabozantinib to everolimus, a standard of care therapy, in 658 patients with advanced RCC whose disease progressed following treatment with a VEGF receptor (VEGFR) tyrosine kinase inhibitor (TKI). The trial's primary endpoint is progression-free survival (PFS), and secondary endpoints include overall survival (OS) and objective response rate (ORR).

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Patients were randomized 1:1 to receive 60 mg of cabozantinib or 10 mg of everolimus daily, and were stratified based on number of prior VEGFR TKI therapies and on commonly applied RCC risk criteria. No crossover was allowed.

As published in the *New England Journal of Medicine*, the trial met its primary PFS and secondary ORR endpoints.[1] Cabozantinib demonstrated a 42% reduction in the rate of disease progression or death as compared with everolimus, with median PFS of 7.4 months versus 3.8 months for everolimus (Hazard Ratio [*]=0.58, 95% Confidence Interval [*] 0.45-0.75, p<0.001).

Following a pre-planned interim analysis that showed a strong trend in OS favoring cabozantinib (HR=0.67, 95% CI 0.51-0.89, p=0.005) but did not reach statistical significance, Exelixis undertook a second interim analysis after consulting with regulatory authorities. The results of this second interim analysis demonstrated a highly statistically significant and clinically meaningful increase in OS for cabozantinib. Exelixis has shared these data with regulators and intends to present them at a medical conference later this year.

Cabozantinib's safety profile was similar to that of other VEGFR TKIs in this patient population. The incidence of adverse events (any grade), regardless of causality, was 100% with cabozantinib and more than 99% with everolimus. Serious adverse events occurred in 40% of cabozantinib patients and 43% of everolimus patients. The rate of treatment discontinuation due to adverse events was low (~10%) in both treatment arms.

About Advanced Renal Cell Carcinoma
The American Cancer Society's 2015 statistics cite kidney cancer as among the top ten most commonly diagnosed forms of cancer among both men and women in the U.S.[2] Clear cell RCC is the most common type of kidney cancer in adults.[3] If detected in its early stages, the five-year survival rate for RCC is high; however, the five-year survival rate for patients with advanced or late-stage metastatic RCC is under 10 percent, with no identified cure for the disease.[4]

Until the introduction of targeted therapies into the RCC setting a decade ago, treatments for metastatic RCC had historically been limited to cytokine therapy (e.g., interleukin-2 and interferon). In the second- and later-line settings, which encompass approximately 17,000 drug-eligible patients in the U.S. and 37,000 globally,[5] two small-molecule therapies and an immune checkpoint inhibitor have been approved. The currently approved small-molecule agents have shown little differentiation in terms of efficacy, demonstrating only modest PFS benefit in patients refractory to sunitinib, a commonly-used first-line therapy.

About Cabozantinib
Cabozantinib is currently marketed in capsule form under the brand name COMETRIQ® in the United States for the treatment of progressive, metastatic MTC, and in the European Union for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC. COMETRIQ is not indicated for patients with RCC. In the METEOR trial, and all other cancer trials currently underway,

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[11] *Choueiri T.K. et al. N Engl J Med 2015;373:1814-23*
[22] *Cancer Facts & Figures 2015. American Cancer Society. Available at http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pd*
[33] *Jonasch et al., BMJ (2014) vol. 349, g4797*
[44] *http://www.cancer.org/cancer/kidneycancer/detailedguide/kidney-cancer-adult-survival-rate*
[55] *ACS Cancer Facts and Figures 2015; Heng et al., Ann Oncol (2012) vol. 23 no. 6; internal data on file; Motzer et al., N Engl J Med (2007) vol. 356 no. 2; NCIN (UK) report, April 2014, Available at http://www.ncin.org.uk/view?rid=2676*

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Exelixis is investigating a tablet formulation of cabozantinib distinct from the COMETRIQ capsule form. The tablet formulation of cabozantinib is the subject of the NDA and MAA for advanced RCC.

Cabozantinib inhibits the activity of tyrosine kinases including VEGF receptors, MET, AXL and RET. These receptor tyrosine kinases are involved in both normal cellular function and in pathologic processes such as oncogenesis, metastasis, tumor angiogenesis and maintenance of the tumor microenvironment.

The European Commission granted COMETRIQ conditional approval for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC. Similar to another drug approved in this setting, the approved indication states that for patients in whom Rearranged during Transfection (RET) mutation status is not known or is negative, a possible lower benefit should be taken into account before individual treatment decisions.

Important Safety Information, including Boxed WARNINGS
WARNING: PERFORATIONS AND FISTULAS, and HEMORRHAGE

Serious and sometimes fatal gastrointestinal perforations and fistulas occur in COMETRIQ-treated patients.
Severe and sometimes fatal hemorrhage occurs in COMETRIQ-treated patients.
COMETRIQ treatment results in an increase in thrombotic events, such as heart attacks.
Wound complications have been reported with COMETRIQ.
COMETRIQ treatment results in an increase in hypertension.
Osteonecrosis of the jaw has been observed in COMETRIQ-treated patients.
Palmar-Plantar Erythrodysesthesia Syndrome (PPES) occurs in patients treated with COMETRIQ.
The kidneys can be adversely affected by COMETRIQ. Proteinuria and nephrotic syndrome have been reported in patients receiving COMETRIQ.
Reversible Posterior Leukoencephalopathy Syndrome has been observed with COMETRIQ.
Avoid administration of COMETRIQ with agents that are strong CYP3A4 inducers or inhibitors.
COMETRIQ is not recommended for use in patients with moderate or severe hepatic impairment.
COMETRIQ can cause fetal harm when administered to a pregnant woman.

Adverse Reactions – The most commonly reported adverse drug reactions (≥25%) are diarrhea, stomatitis, palmar-plantar erythrodysesthesia syndrome (PPES), decreased weight, decreased appetite, nausea, fatigue, oral pain, hair color changes, dysgeusia, hypertension, abdominal pain, and constipation. The most common laboratory abnormalities (≥25%) are increased AST, increased ALT, lymphopenia, increased alkaline phosphatase, hypocalcemia, neutropenia, thrombocytopenia, hypophosphatemia, and hyperbilirubinemia.

Please see full U.S. prescribing information, including Boxed WARNINGS, at www.COMETRIQ.com/downloads/Cometriq_Full_Prescribing_Information.pdf

Please refer to the full European Summary of Product Characteristics for full European Union prescribing information, including contraindication, special warnings and precautions for use at www.sobi.com once posted.

About Ipsen
Ipsen is a global specialty-driven biotechnological group with total sales exceeding €1.4 billion in 2015. Ipsen sells more than 20 drugs in more than 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its fields of expertise cover oncology, neurosciences and endocrinology (adult &

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pediatric). Ipsen's commitment to oncology is exemplified through its growing portfolio of key therapies improving the care of patients suffering from prostate cancer, bladder cancer and neuro-endocrine tumors. Ipsen also has a significant presence in primary care. Moreover, the Group has an active policy of partnerships. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins, located in the heart of the leading biotechnological and life sciences hubs (Les Ulis/Paris-Saclay, France; Slough/Oxford, UK; Cambridge, US). In 2015, R&D expenditure totaled close to €193 million, representing about 13% of Group sales. The Group has more than 4,600 employees worldwide. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and eligible to the "Service de Règlement Différé" ("SRD"). The Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit www.ipsen.com.

About Exelixis

Exelixis, Inc. is a biopharmaceutical company committed to developing small molecule therapies for the treatment of cancer. Exelixis is focusing its development and commercialization efforts primarily on cabozantinib, an internally discovered inhibitor of multiple receptor tyrosine kinases. Another Exelixis-discovered compound, COTELLIC™ (cobimetinib), a selective inhibitor of MEK, has been approved in Switzerland, the United States, the European Union, and Canada, and is being evaluated by Roche and Genentech (a member of the Roche Group) in a broad global development program under a collaboration with Exelixis. For more information, please visit the company's website at www.exelixis.com.

Exelixis Forward-Looking Statement Disclaimer

This press release contains forward-looking statements, including, without limitation, statements related to: the business and financial terms of the collaboration agreement for cabozantinib with Ipsen, including, the division of commercialization rights, development plans and Exelixis' eligibility to receive regulatory and commercial milestones and royalties; Exelixis' plan to continue its discussions to partner commercial rights for cabozantinib in Japan; the potential for cabozantinib to become a key oncology product in Europe and the impact of the transaction on the growth of Ipsen; advanced HCC as a future potential commercial indication for cabozantinib and the timing for anticipated top-line results from CELESTIAL; the impact of the collaboration with Ipsen on Exelixis' plan to maximize the potential for cabozantinib on a global basis; Exelixis' plan to stay focused on the potential launch of cabozantinib in advanced RCC in the United States; advanced RCC as Exelixis' immediate priority; Exelixis' and Ipsen's commitment to exploring and potentially developing cabozantinib in a variety of cancers; the eligibility for an expedited review of Exelixis' MAA for cabozantinib in advanced RCC by the EMA and Exelixis' plans to transfer sponsorship of the MAA to Ipsen; Exelixis' plans to transition the commercialization rights to COMETRIQ outside of the U.S. from Sobi to Ipsen; and Exelixis' intent to present data from the second interim analysis of OS for METEOR at a medical conference later this year. Words such as "will," "potential," "future," "continue," "eligible," "priority," "committed," "plans," "anticipates," "intends," 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 clinical, therapeutic and commercial potential of cabozantinib; Exelixis' dependence on its relationship with Ipsen, including, the level of Ipsen's investment in the resources necessary to successfully commercialize cabozantinib in the territories where it is approved; Exelixis' ability to maintain its rights under the Ipsen collaboration; risks and uncertainties

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related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; the ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; Exelixis' ability to judge the proper size and level of experience of the commercialization teams required to support the launch of cabozantinib for advanced RCC; unanticipated complications associated with the transition of the COMETRIQ commercialization rights from Sobi to Ipsen; the availability of data at the referenced times; 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 10, 2015, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' annual report on Form 10-K expected to be filed with the SEC on February 29, 2016. 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.

Ipsen Forward-Looking Statement Disclaimer

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words "believes," "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from generic products that might translate into a loss of market share. Furthermore, the Research and Development process involves several stages each of which involves the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favorable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The Group also depends on third parties to

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develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group cannot be certain that its partners will fulfill their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. The Group expressly disclaims any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers.

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Exhibit 10.2

FIRST AMENDMENT TO COLLABORATION AND LICENSE AGREEMENT

This **FIRST AMENDMENT TO THE COLLABORATION AND LICENSE AGREEMENT** (the "**Amendment**") is entered into as of December 20, 2016 (the "**Amendment 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 **Ipsen Pharma SAS**, a French corporation having an address at 65 Quai Georges Gorse, 92100 Boulogne-Billancourt, France ("**Licensee**"). Exelixis and Licensee may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

RECITALS

WHEREAS, Exelixis and Licensee are parties to that certain Collaboration and License Agreement dated February 29, 2016 (the "**License Agreement**"), under which the Parties have been collaborating on the development and commercialization of cabozantinib; and

WHEREAS, the Parties desire to enter into this Amendment to expand the territory in which Licensee has the right to develop and commercialize cabozantinib and amend the continuing rights and obligations of the Parties under the License Agreement, all on the terms and conditions set forth below.

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

1. DEFINITIONS.

1.1 Section 1.30 of the License Agreement is hereby deleted in its entirety and replaced with the following:

1.30 "**Exelixis Territory**" means the U.S. and Japan.

1.2 Section 1.55 of the License Agreement is hereby deleted in its entirety and replaced with the following:

1.55 "**Major Market Countries**" means [*].

1.3 Section 1.69 of the License Agreement is hereby deleted in its entirety and replaced with the following:

1.69 "**Region**" means, individually and collectively, the following regions: [*].

1.4 Section 1.71 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"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, the EMA and Health Canada or other foreign equivalent. For countries where governmental approval is required for pricing or reimbursement for a pharmaceutical product to be reimbursed by national health insurance (or its local equivalent), Regulatory Authority shall also include any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

1.5 "**Health Canada**" means the federal department of the government of Canada having the authority to regulate the sale of medicinal or pharmaceutical products, or any successor agency thereof.

1.6 Unless otherwise defined in this Amendment, all capitalized terms have the meaning as defined in the License Agreement.

2. DEVELOPMENT

2.1 Canada Studies. If any Regulatory Authority in Canada requires one or more additional studies to support any MAA submitted by Licensee for the Product in Canada that are exclusively for the benefit of Canada (the "**Canada Studies**"), such studies shall be deemed Licensee Only Development Work and subject to Licensee's applicable obligations set forth in the License Agreement, including, without limitation, those obligations set forth in Sections 4.2, 4.5(e), 4.6, 4.7(a), and 4.8. In accordance with Section 3.2(h) of the License Agreement, the JDC shall prepare an amendment(s) to the GDP with respect to any Canada Studies and submit such amendment(s) to the JSC for approval. Exelixis shall, as may be required to enable Licensee to be the Sponsor of the Canada Studies, be subject to Exelixis' applicable obligations set forth in Section 5.1(b) of the License Agreement. Exelixis shall have the right to use the Data of the Canada Studies generated by Licensee to support its own Development, Regulatory Approval or Commercialization in the Exelixis Territory subject to Section 9.2(b) of the License Agreement.

2.2 Country-Specific Development Work. The phrase "Canada or" in the first sentence of Section 4.5(e) is hereby deleted.

3. REGULATORY ACTIVITIES

3.1 Regulatory Filings. If any Canada Studies are included in the GDP, the GDP shall specify that Licensee shall apply for and hold Regulatory Filings in Canada.

3.2 PVA. As soon as reasonably practicable after the Amendment Effective Date, the Parties shall amend the PVA as necessary to address the modification herein to the Parties' respective territories.

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4. MANUFACTURE AND SUPPLY

4.1 Supply Agreement. As soon as reasonably practicable after the Amendment Effective Date, the Parties shall amend the Supply Agreement as necessary to address the modification herein to the Parties' respective territories. In particular, the Parties agree that the Supply Agreement will be amended to add [*] reports from the below-referenced tracking system detailing the distribution and sale of product supplied for Canada.

4.2 The following is hereby added to the License Agreement as Sections 2.8(e)-(f):

(e) To enforce the Parties' respective obligations set forth in Section 2.8(e) of the Agreement, to the extent permitted by Applicable Law, neither Party shall, and shall ensure that its respective Affiliates, permitted Sublicensees, and Third Party distributors will not, either directly or indirectly, advertise, promote, or market Products, including via the Internet, to any Third Party or place of business, residence, or shipping address in the other Party's territory for the duration of the Royalty Term. The foregoing shall restrict either Party, to the extent permitted by Applicable Law, from engaging in any form of direct or indirect solicitation, advertisement, or promotion in the other Party's territory. Each Party shall promptly, without any right to remuneration or compensation, forward to the other Party all inquiries regarding the Product by persons or entities whose place of business, residence, or shipping address is in the other Party's territory.

(f) Licensee will [*]. In the event that Exelixis or Licensee [*], Licensee shall [*].

5. FINANCIAL PROVISIONS

5.1 Amendment Execution Payment. In consideration of the expanded license rights granted by Exelixis to Licensee by virtue of this Amendment, Licensee shall make a one-time, non-refundable, noncreditable payment to Exelixis of ten million dollars ($10,000,000) within five (5) days after execution of this Amendment.

5.2 Development Milestone Payments. The following is hereby added as Section 9.3(c) of the License Agreement:

9.3(c) Development Milestones Specific to Canada. Subject to the remainder of this Section 9.3(c), Licensee 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 Licensee, Exelixis, or their Affiliates, licensee(s) of Exelixis or Sublicensees):

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Milestone Event	Milestone Payment
Milestone A: MAA Approval by Health Canada (*i.e.*, receipt of a "Notice of Compliance") for a Product for RCC (2nd line)	$5,000,000
Milestone B: MAA Approval by Health Canada for a Product for RCC (1st line)	$3,000,000*
Milestone C: MAA Approval by Health Canada (*i.e.*, receipt of a "Notice of Compliance") for a Product for HCC (2nd line)	$2,000,000
Milestone D: MAA Approval by Health Canada (*i.e.*, receipt of a "Notice of Compliance") for a Product for the first indication other than RCC or HCC	$[*]
Milestone E: MAA Approval by Health Canada (*i.e.*, receipt of a "Notice of Compliance") for a Product for the second indication other than RCC or HCC	$[*]

(i) *With respect to a Product, if Licensee achieves Milestone A, and as part of such Milestone A, RCC (1st line) is also included in the claims section of the approved label of Milestone A and allows Ipsen to promote the Product for use in RCC (1st line), then Licensee shall pay Exelixis the milestone payment corresponding to Milestone B in addition to the milestone amount owed for achievement of Milestone A. For clarity, in no event shall Licensee be obligated to pay to Exelixis more than a total of $8,000,000 for the achievement of Milestones A and B with respect to any one Product.

(ii) Subject to Section 9.3(c)(i), each milestone payment shall be paid once for the applicable events described above for each different applicable Product.

5.3 Net Sales Milestones. Section 9.4(b) is hereby deleted in its entirety and replaced with the following:

9.4(b)(i) Net Sales Milestones for Licensee Territory Excluding Canada. Licensee 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 Licensee Territory, but excluding the Net Sales of all Products in Canada, 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 Licensee under this Section 9.4(b)(i) (the "**Previously Achieved Commercial 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 Commercial Milestone. For the avoidance of doubt, each payment in this Section 9.4(b)(i) shall be payable once only, regardless of the number of times such milestone is subsequently achieved.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Aggregate Net Sales of all Products in the Licensee Territory Excluding Canada in Any 4 Consecutive Calendar Quarters	Milestone Payments
Equal or exceed $100 million	$25 million
Equal or exceed $250 million	$50 million
Equal or exceed $[*]	$[*]
Equal or exceed $[*]	$[*]
Equal or exceed $[*]	$[*]

9.4(b)(ii) Net Sales Milestones for Canada. Licensee 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 Canada 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 Licensee under this Section 9.4(b)(ii) (the "**Previously Achieved Commercial Milestone for Canada**"), 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 (4^{th}) Calendar Quarter which served as the period to determine the reaching of the Net Sales amount triggering the Previously Achieved Commercial Milestone for Canada. For the avoidance of doubt, each payment in this Section 9.4(b)(i) shall be payable once only, regardless of the number of times such milestone is subsequently achieved.

Aggregate Net Sales of all Products in Canada in Any 4 Consecutive Calendar Quarters	Milestone Payments
Equal or exceed CAD$[*]	CAD$[*]
Equal or exceed CAD$[*]	CAD$[*]
Equal or exceed CAD$[*]	CAD$[*]

(A) For clarity, the amounts set forth in this Section 9.4(b)(ii) refer to Canadian dollars.

5.4 Notice and Payment for Net Sales Milestones. Section 9.4(c)(ii) is hereby deleted in its entirety and replaced with the following:

(ii) As part of the report in Section 10.1, Licensee shall provide written notice to Exelixis if (1) the aggregated Net Sales of all Products in the Licensee Territory, but excluding the Net Sales of all Products in Canada, in any four (4) consecutive Calendar Quarters first reach the values set forth in Section 9.4(b)(i), or (2) the aggregated Net Sales of all Products in Canada in any four (4) consecutive Calendar Quarters first reach the values set forth in Section 9.4(b)(ii), and Licensee shall pay to Exelixis the corresponding Net Sales milestone payment within [*] after the end of the Calendar Quarter.

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5.5 Royalty Rate. Section 9.5(a) is hereby deleted in its entirety and replaced with the following:

9.5(a)(i) Royalty Rate for Licensee Territory Excluding Canada. Subject to the other terms of this Section 9.5, during the Royalty Term, Licensee shall make quarterly non-refundable, non-creditable royalty payments to Exelixis on the annual Net Sales of all Products sold in the Licensee Territory, but excluding the annual Net Sales of all Products sold in Canada, at the applicable rate set forth below:

Annual Net Sales of all Products in the Licensee Territory Excluding Canada	Royalty Rate
Portion less than or equal to $[*]	22%
Portion greater than $[*] and less than or equal to $[*]	[*]%
Portion greater than $[*]	26%

9.5(a)(ii) Royalty Rate for Canada. Subject to the other terms of this Section 9.5, during the Royalty Term Licensee shall make quarterly non-refundable, non-creditable royalty payments to Exelixis on the annual Net Sales of all Products sold in Canada at the applicable rate set forth below:

Annual Net Sales of all Products in Canada	Royalty Rate
Portion less than or equal to CAD$30 million	22%
Portion greater than CAD$30 million and less than or equal to CAD$[*]	[*]%
Portion greater than CAD$[*]	26%

(A) For clarity, the annual Net Sales amounts set forth in this Section 9.4(a)(ii) refer to Canadian dollars.

6. INTELLECTUAL PROPERTY

6.1 Product Trademarks. The following is hereby added as Section 11.6(a)(i):

(i) Without limiting the generality of the foregoing Section 11.6(a), the Parties shall use the trademark Cabometyx® for the Product in Canada to the extent that such trademark is approved for use with the Product by Health Canada or other applicable Regulatory Authority. If Exelixis is unable to obtain or register Cabometyx® for use with the Product in Canada, the Parties shall collaborate to select another Product Mark to be used for the Product in Canada. In accordance with Section 11.6(a), Exelixis shall own the Product Marks used for the Product in Canada and all goodwill in such Products Marks shall accrue to Exelixis.

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7. GENERAL PROVISIONS

7.1 Effect of Amendment. Except as provided in Sections 9.4(b)(ii) and 9.5(a)(ii), all references in the Agreement to dollars or "$" shall remain United States Dollars. Except as expressly modified herein, all terms and conditions set forth in the License Agreement, as in effect on the Amendment Effective Date, shall remain in full force and effect.

7.2 Entire Agreement. The License Agreement as modified by this Amendment is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to its subject matter. They supersede all prior and contemporaneous agreements and communications, whether written or oral, of the Parties regarding this subject matter.

7.3 Severability. If, for any reason, any part of this Amendment is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Amendment. All remaining portions shall remain in full force and effect as if the original Amendment had been executed without the invalidated, unenforceable, or illegal part.

7.4 Counterparts; Electronic or Facsimile Signatures. This Amendment 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 Amendment 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}

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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

EXELIXIS, INC.	**IPSEN PHARMA S.A.S**
By: /s/ Michael Morrissey	**By: /s/ Christophe Jean**
Name: Michael Morrissey, PhD	**Name: Christophe Jean**
Title: President & CEO	**Title: EVP Corporate Strategy & Business Development**

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.3

SECOND AMENDMENT TO COLLABORATION AND LICENSE AGREEMENT

This **SECOND AMENDMENT TO THE COLLABORATION AND LICENSE AGREEMENT** (the "**Second Amendment**") is entered into as of September 14, 2017 (the "**Second Amendment 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 **Ipsen Pharma SAS**, a French corporation having an address at 65 Quai Georges Gorse, 92100 Boulogne-Billancourt, France ("**Licensee**"). Exelixis and Licensee may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

RECITALS

WHEREAS, Exelixis and Licensee are parties to that certain Collaboration and License Agreement dated February 29, 2016, as amended by Amendment No. 1, dated effective December 20, 2016 (together, the "**License Agreement**"), under which the Parties have been collaborating on the development and commercialization of cabozantinib; and

WHEREAS, the Parties desire to enter into this Second Amendment to amend the timing of a certain milestone payment under the License Agreement, all on the terms and conditions set forth below.

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

1. FINANCIAL PROVISIONS

1.1 Development Milestone Payments. Section 9.3(b) of the License Agreement is hereby amended and restated to read in full as follows:

> "**9.3(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 9.3 by such Party, its Affiliates, or its Sublicensees. Licensee shall pay to Exelixis the applicable development milestone payments within [*] after the delivery or receipt of such notice. Notwithstanding the foregoing sentence, Licensee shall pay to Exelixis the Milestone #2 payment (First MAA filing with the EMA) for the Tier 1 Additional Indication ($25,000,000) either within [*] after the delivery or receipt of notice, or on [*], whichever is later."

2. GENERAL PROVISIONS

2.1 Effect of Amendment. Except as expressly modified herein, all terms and conditions set forth in the License Agreement, as in effect on the Second Amendment Effective Date, shall remain in full force and effect.

2.2 Entire Agreement. The License Agreement as modified by this Second Amendment is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to its subject matter. They supersede all prior and contemporaneous agreements and communications, whether written or oral, of the Parties regarding this subject matter.

2.3 Severability. If, for any reason, any part of this Second Amendment is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Second Amendment. All remaining portions shall remain in full force and effect as if the original Second Amendment had been executed without the invalidated, unenforceable, or illegal part.

2.4 Counterparts; Electronic or Facsimile Signatures. This Second Amendment 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 Second Amendment 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}

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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

EXELIXIS, INC.	**IPSEN PHARMA S.A.S**
By: /s/ Christopher J. Senner	By: /s/ François Garnier
Name: Christopher J. Senner	Name: François Garnier
Title: EVP and CFO	Title: Executive Vice President, General Counsel

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.4

THIRD AMENDMENT TO COLLABORATION AND LICENSE AGREEMENT

This **THIRD AMENDMENT TO THE COLLABORATION AND LICENSE AGREEMENT** (the "**Third Amendment**") is entered into as of October 26, 2017 (the "**Third Amendment 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 **Ipsen Pharma SAS**, a French corporation having an address at 65 Quai Georges Gorse, 92100 Boulogne-Billancourt, France ("**Licensee**"). Exelixis and Licensee may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

RECITALS

Whereas, Exelixis and Licensee are parties to that certain Collaboration and License Agreement dated February 29, 2016, as amended by Amendment No. 1, dated effective December 20, 2016, and Amendment No. 2 dated effective September 14, 2017 (together, the "**License Agreement**"), under which the Parties have been collaborating on the development and commercialization of cabozantinib; and

Whereas, the Parties desire to enter into this Third Amendment to update certain definitions and manufacturing responsibilities under the License Agreement, all on the terms and conditions set forth below.

Now, Therefore, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

1.1 Unless otherwise defined in this Third Amendment, all capitalized terms have the meaning as defined in the License Agreement.

1.2 "Cost of Goods" Definition. The fourth sentence of Section 1.19 of the License Agreement is hereby amended and restated to read as follows:

"Direct labor costs shall include the cost of: [*]."

2. MANUFACTURE AND SUPPLY

2.1 Manufacture and Supply. The third and fourth sentences of Section 7.1 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"It is anticipated that Exelixis will supply commercial Product to Licensee in final, labeled packaged form. Exelixis shall be responsible for packaging and labeling for all countries in the Licensee Territory."

3. GENERAL PROVISIONS

3.1 Effect of Amendment. Except as expressly modified herein, all terms and conditions set forth in the License Agreement, as in effect on the Third Amendment Effective Date, shall remain in full force and effect.

3.2 Entire Agreement. The License Agreement as modified by this Third Amendment is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to its subject matter. They supersede all prior and contemporaneous agreements and communications, whether written or oral, of the Parties regarding this subject matter.

3.3 Severability. If, for any reason, any part of this Third Amendment is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Third Amendment. All remaining portions shall remain in full force and effect as if the original Third Amendment had been executed without the invalidated, unenforceable, or illegal part.

3.4 Counterparts; Electronic or Facsimile Signatures. This Third Amendment 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 Third Amendment 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}

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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

EXELIXIS, INC.	IPSEN PHARMA S.A.S
By: /s/ Michael M. Morrissey	By: /s/ Christophe Jean
Name: Michael M. Morrissey, Ph.D.	Name: Christophe Jean
Title: President and CEO	Title: EVP Corporate Strategy & Business Development

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.5

SUPPLY AGREEMENT

This **SUPPLY AGREEMENT** (the "**Supply Agreement**") is entered into as of February 29, 2016 (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 **IPSEN PHARMA SAS**, a French corporation having an address at 65 Quai Georges Gorse, 92100 Boulogne-Billancourt, France ("**Licensee**"). Exelixis and Licensee may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Exelixis, a biopharmaceutical company, is developing its proprietary compound known as cabozantinib for the treatment of cancer;

WHEREAS, Exelixis and Licensee are parties to a certain Collaboration and License Agreement of even date hereof (the "**Collaboration and License Agreement**"), under which Exelixis has granted Licensee the right to develop and commercialize cabozantinib outside the U.S., Canada, and Japan; and

WHEREAS, the Collaboration and License Agreement contemplates that Exelixis will manufacture and supply cabozantinib to Licensee for development and commercial use, and Exelixis is willing to manufacture and supply cabozantinib to Licensee, on the terms and conditions set forth below.

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, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Capitalized terms used in this Supply Agreement but not defined herein shall have the meanings set forth in the Collaboration and License Agreement.

1.1 "**Affiliate**" means, 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.

1.2 "**Batch**" means the quantity of a Product produced in a single production run of such Product.

1.3 "**Business Day**" means a day that is not a Saturday, Sunday, or a day on which banking institutions in San Francisco, California, USA are authorized by Law to remain closed.

1.4 **"Claims"** means any and all Third Party claims, suits, proceedings, damages, expenses (including court costs and reasonable attorneys' fees and expenses) and recoveries against a Party.

1.5 "**Collaboration and License Agreement**" has the meaning set forth in the Recitals.

1.6 "**Compound**" means cabozantinib, having the chemical structure set forth in Exhibit A of the Collaboration and License Agreement, including any pharmaceutically acceptable salt form of cabozantinib.

1.7 **"Cost of Goods"** or **"COG"** means, with respect to any Compound or Product, the fully burdened cost to manufacture such Compound or Product, which means: (a) in the case of [*]; and (b) in the case of [*]. Actual unit costs shall consist of [*]. Direct labor costs shall include the cost of: [*]. Manufacturing [*] shall include [*].

1.8 "**Drug Substance**" means cabozantinib, having the chemical structure set forth in Exhibit A of the Collaboration and License Agreement.

1.9 "**EMA**" means the European Medicines Agency or its successor.

1.10 **"Exelixis Indemnitees"** means Exelixis and its Affiliates and their respective officers, directors, employees, and agents.

1.11 "**Exelixis Territory**" means the U.S., Canada, and Japan.

1.12 "**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.

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

1.14 "**Field**" means all indications and uses in humans and animals.

1.15 "**Finished Product**" means any Product in appropriate final form, packaged and labeled and ready for its intended use (i.e., sale to the end-user, use as part of an Expanded Access Program, use in clinical trials or other development work or use as a sample).

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

1.16 "**Good Distribution Practice**" means, to the extent applicable, the then-current Good Distribution Practice Guidelines issued by the European Commission to ensure that the level of quality determined by GMP is maintained throughout the distribution network, as set forth in Commission Guidelines 2013/C 343/01 and any and all related Directives, as may be amended from time to time.

1.17 "Good Manufacturing Practices," "**cGMPs**" or "**GMP**" means, to the extent applicable, the then-current Good Manufacturing Practices required by the FDA and/or EMA, for the manufacture and testing of pharmaceutical materials, as set forth in 21 CFR Parts 11, 210 and 220 and Directives 2003/94/EC and 2001/83/EC, as each may be amended from time to time, and comparable laws or regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by other Regulatory Authorities.

1.18 "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).

1.19 "Information" means any data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data, and data resulting from non-clinical studies), CMC information, stability data, and other study data and procedures.

1.20 "Laws" means all laws, statutes, rules, regulations, ordinances, and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city, or other political subdivision, domestic or foreign.

1.21 "Licensee Indemnitees" means Licensee and its Affiliates and their respective directors, officers, employees, and agents.

1.22 "Licensee Territory" means the world outside the Exelixis Territory.

1.23 "**Manufacture**" means with respect to the period prior to the implementation of the Transition Plan as set forth in Section 2.4(e), all activities related to the manufacturing of the Compound and Products, in final, labeled, packaged form for commercial use, including in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, ongoing stability tests and regulatory activities related to any of the foregoing. For the period after the Transition Plan, with regard specifically to packaging, shall be primary packaged bulk tablets, rather than labelled packaged form for commercial use. "**Manufacturing**" has a correlative meaning.

1.24 "**Order Forecast**" has the meaning set forth in Section 2.2(a).

1.25 "**Product**" means any pharmaceutical product containing the Compound as an active ingredient, in any form, presentations, dosage, or formulation, including but not limited to Cometriq.

1.26 "**Quality Agreement**" has the meaning set forth in Section 2.6.

1.27 "**REACH**" shall have the meaning set forth in Section 4.5.

1.28 **"Recall**" means a recall, withdrawal, or correction (including the dissemination of relevant information) of any Product in a Party's territory that is (a) required by a Regulatory Authority of competent jurisdiction, or (b) is deemed advisable by the representative of Licensee's Quality department in its sole discretion in Licensee Territory, or (c) is deemed advisable by the representative of Exelixis' Quality department in the Exelixis Territory.

1.29 **"Regulatory Approval**" means any and all approvals (including MAA Approval, and Pricing and Reimbursement Approval, if applicable), 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.

1.30 **"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 EMA. For countries where governmental approval is required for pricing or reimbursement for a pharmaceutical product to be reimbursed by national health insurance (or its local equivalent), Regulatory Authority shall also include any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

1.31 **"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.

1.32 "**Specification**" means the written specification for each Product, as the same may be amended from time to time by Exelixis, or upon Licensee's reasonable request in accordance with requirements of Regulatory Authorities in the Licensee Territory. Specifications may be required to be different for a Product for use in different countries due to individual Regulatory Authority requirements in such countries.

1.33 "**Stockout Period**" means a period during which Licensee, as a result of failure of Exelixis to supply Product, has no commercial inventory available to supply the market in the Licensee Territory. Inventory stockouts arising from Licensee's failure to maintain the [*] safety stock in accordance with the Supply Agreement shall not give rise to a Stockout Period.

1.34 **"Term"** has the meaning set forth in Section 10.1.

1.35 "**Third Party**" means any entity other than Exelixis or Licensee or an Affiliate of Exelixis or Licensee.

1.36 "**Transfer Price**" has the meaning set forth in Section 3.1.

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

ARTICLE 2
PRODUCT SUPPLY

2.1 Purchase and Sale. Pursuant to the terms and conditions of this Supply Agreement, Exelixis (either itself or through its Affiliates or Third Party subcontractors) shall use Commercially Reasonable Efforts to Manufacture and supply Products to Licensee in such quantities as Licensee shall order pursuant to and in accordance with this Article 2, and Licensee shall purchase from Exelixis all of Licensee's and its Affiliates' and Sublicensees' requirements for Products for development and commercialization in the Field in the Licensee Territory pursuant to and in accordance with the Collaboration and License Agreement. For clarity, Exelixis may perform its obligations under this Supply Agreement through one or more Third Party subcontractors, provided that Exelixis remains responsible for the work allocated to, and payment to, such subcontractors as it selects, to the same extent it would if it had done such work itself.

2.2 Order Forecasts.

(a) Rolling Forecast. On or prior to [*] of each Calendar Quarter during the Term of this Supply Agreement, Licensee shall provide Exelixis a rolling forecast of the quantity of Products to be used for commercialization that Licensee plans to order during the [*] period commencing the following Calendar Quarter, itemizing the applicable quantity for each form of Product (i.e., dosage strength and packaging configuration) ("**Order Forecast**"). The Order Forecast shall be made in good faith for budget and capacity planning purposes only and shall be non-binding on Licensee and Exelixis, except as provided in Section 2.2(b). The Parties shall discuss and review the Order Forecast at each regularly scheduled meeting of the JSC established by the Parties under the Collaboration and License Agreement (or by a subcommittee established by the JSC to oversee the manufacture and supply of the Product). The Order Forecast will be in substantially the form attached hereto as **Exhibit A**.

(b) Binding Commitment. The [*] of each Order Forecast shall constitute a binding commitment for Licensee to purchase, pursuant to Section 2.3(a), [*] of the quantities for each form of Finished Product specified therein and Licensee shall be required to order such quantities pursuant to Section 2.3(a). The [*] of each Order Forecast shall constitute a binding commitment for Licensee to purchase, pursuant to Section 2.3(a), [*] of each form of Finished Product specified therein. For clarity, the numbers set out in the following [*] of the Order Forecast constitute the non-binding forecast of Licensee's expected requirements.

2.3 Purchase Orders; Delivery Terms.

(a) Purchase Orders. On or before the [*] of each Calendar Quarter during the Term of this Supply Agreement, Licensee shall submit to Exelixis a binding purchase order (a **"Purchase Order**") for Product to be delivered during the next Calendar Quarter as follows:

(i) with respect to commercial supply, in quantities [*] to those set forth for such Calendar Quarter in the Order Forecast, and

(ii) with respect to development supply, in quantities [*] with those projected for use in clinical development by Licensee as set forth in the Global Development Plan (as defined in the Collaboration and License Agreement), as well as any comparator drugs set forth in the Global Development Plan as to be supplied by Exelixis to Licensee.

Exelixis shall accept or reject each Purchase Order in writing within [*] after its receipt of such Purchase Order; *provided, however*, that Exelixis shall accept such Purchase Order, if the quantities of Product ordered in such Purchase Order are consistent with the quantities set forth in subsection (i) and/or (ii), as applicable.

(b) Additional Quantities. In the event Licensee desires to obtain quantities of Product in a particular Calendar Quarter in excess of the quantities specified in the Order Forecast after such forecast became binding, Licensee shall notify Exelixis in writing the Parties will discuss in good faith as to whether Exelixis may be able to supply Licensee with such additional quantities, provided that Exelixis shall have the right to accept and/or reject such order at its sole discretion.

(c) Delivery and Shipping Terms. Purchase Orders submitted for quantities of Product that are in accordance with Section 2.3(a) and/or Section 2.3(b) will be binding on both Parties after acceptance in writing by Exelixis; provided, however, that should Exelixis neither reject a Purchase Order nor provide written confirmation of acceptance within [*] of receipt, Exelixis shall be deemed to have accepted the Purchase Order effectively. The Purchase Order will specify a single delivery date for such order to be delivered in such Calendar Quarter, but will in no event be a date sooner than [*]. By way of example, a Purchase Order submitted on [*] would specify the quantity of Product ordered for delivery in the [*] Calendar Quarter of [*], with a delivery date no sooner than [*]. Exelixis shall deliver all Products [*]. Exelixis shall be responsible for obtaining all licenses or other authorizations for the exportation of such shipments and shall supply Licensee with the documentation required for filing or claiming credit or deduction for any applicable taxes and/or duties. Licensee shall be responsible for

obtaining all freight, handling, insurance, and shipping expenses for such shipments, and shall be the importer of record and responsible for all duties and taxes for such shipments, and shall be responsible for obtaining all distribution licenses for the Products.

(d) Separate Contracts. Each Purchase Order will constitute a separate contract for the supply of Products on the terms of this Agreement (and excluding all other terms and conditions including any set out or referred to in any Purchase Order). In the event of a conflict between a Purchase Order and the terms of this Agreement, the terms of this Agreement will govern.

2.4 Supply.

(a) Documentation. Exelixis shall establish and maintain any necessary drug master files, standard operating procedures, protocols, and master batch records for the Manufacturing of the Products. Exelixis shall, in connection with each shipment of Product to Licensee, provide to Licensee the certificate of compliance, certificate of analysis, completed batch records and any other documentation as may be required in the Quality Agreement with respect to such shipment.

(b) Traceability. Exelixis shall mark the Product supplied to Licensee with a lot number for the purposes of traceability. Licensee shall record the lot number of each Product used for each promotion and marketing event, distributed to each named patient in an Expanded Access Program, or sold to each customer, and shall retain all such records for [*] after the date of termination or expiration of this Supply Agreement to facilitate in the event of a Recall under Section 5.9 of the Collaboration and License Agreement.

(c) Form of Supply. Exelixis shall supply Licensee with Finished Product in finished, labeled form at Licensee's cost and expense. Exelixis shall supply Product for commercialization in the Licensee Territory according to Licensee's written instructions specifying desired quantities of Product in each of the available dosages and product configurations (i.e. bottles and/or blister strips) to meet the requirements for the Regulatory Authorities in each applicable jurisdiction. Licensee shall be responsible for ensuring that the Finished Product conforms with all applicable Laws and Regulatory Approvals for each applicable jurisdiction within Licensee Territory.

(d) Finished Product Release. Prior to implementation of the Transition Plan as such term is defined in Section 2.4(e), Exelixis (by itself or through its contract manufacturer) shall conduct release tests of the Product for Licensee, and Exelixis shall supply Licensee with Finished Product release documentation so that Licensee may fulfil its obligations as the Marketing Authorization Holder in the applicable Licensee Territory.

(e) Transition Plan. Licensee shall develop, and submit to JSC for review and approval, a transition plan ("**Transition Plan**") by [*]. The Transition Plan shall provide for Licensee's assumption of responsibility for primary packaged bulk tablets, including but not limited to labeling, Finished Product release, and QP release to market by [*]. Such Transition Plan will take effect at [*] unless otherwise agreed by the JSC, and this Supply Agreement will be updated to reflect this shift of responsibilities between the Parties. The Parties further agree

that Licensee will concurrently assume contractual responsibility for the abovementioned activities with Exelixis' commercial manufacturer, Patheon, Inc. ("Patheon") by entering into privity of contract with Patheon. In the event that Licensee chooses to assume the responsibility contemplated in this section through any other means of manufacture other than a direct contract with Patheon, Licensee agrees to provide Exelixis with at least [*] prior written notice in order to enable Exelixis to fulfill its own notice requirements to Patheon.

(f) Product Shelf Life. The Product supplied by Exelixis to Licensee hereunder shall have a remaining shelf life of [*] of approved shelf life upon delivery pursuant to Section 2.3(c).

(g) Inventory Management; Safety Stock. Each Party shall manage its inventory in a manner that maximizes the remaining shelf life of its inventory. Licensee shall carry a reasonable quantity of inventory of the Finished Product, and Exelixis shall carry a reasonable quantity of raw materials, including API, which may be used in the event of an interruption to the supply chain. The quantity of such safety stock shall be sufficient to cover the quantity set forth in the Order Forecast for the next [*]. The Parties shall replace and replenish the safety stock continuously on a first to expire, first out basis. Each Party shall be responsible for the cost of maintaining its own safety stock.

2.5 Inspection and Acceptance.

(a) Shortages. Licensee shall notify Exelixis in writing of any shortage in any shipment of Product within [*] of receipt. In the event of an undisputed shortage, Exelixis shall make up the shortage at no cost to Licensee, within [*] if replacement Finished Product stock is available, or, if replacement stock is unavailable at such time, as soon as reasonably practicable after it becomes available.

(b) Non-Conforming Product.

(i) Licensee shall inspect all shipments of Product promptly upon receipt, and shall notify Exelixis in writing in reasonable detail within [*] of receipt if Licensee is rejecting any Product that fails to conform to Exelixis' warranties set forth in Sections 8.2(a) or 8.2(b). All Product not rejected within such [*] period will be deemed accepted.

(ii) If Licensee notifies Exelixis of any nonconformity of any Product in accordance with Section 2.5(b)(i), Exelixis shall have the right to inspect the Product in question and Licensee shall cooperate with Exelixis' inspection, including providing Exelixis with samples of the Product in question for testing upon request. If Exelixis agrees with such notice of nonconformity, Exelixis shall, at its discretion and expense, either: (i) replace such Product, at no additional expense to Licensee, as soon as reasonably practicable after receipt of notification of such nonconformity or (ii) refund any portion of the applicable Transfer Price that has already been paid.

(iii) In the event that Exelixis disagrees with Licensee that a Product does not conform to Exelixis' warranties set forth in Sections 8.2(a) or 8.2(b), or considers that

the defect was caused by occurrences after the delivery of the Product to Licensee, it may require a sample of the allegedly nonconforming Product to be delivered to a mutually acceptable independent testing laboratory for testing or, in the case of a dispute concerning compliance with GMP, an independent consultant for evaluation. Except in the case of manifest error, the determination of the laboratory or consultant as to whether the Product is nonconforming will be final and binding on the Parties. The fees and expenses of such laboratory testing or consultant, as the case may be, shall be borne entirely by the Party against whom such laboratory's or consultant's determination is made. If, as the case may be, such determination is against Exelixis, then Exelixis shall either refund the Transfer Price paid by Licensee for such Product or replace such Product, at no additional cost to Licensee, as soon as reasonably possible, but in no event later than [*] if replacement Product stock is available, or if replacement Product stock is unavailable at such time, as soon as reasonably practical after it becomes available. If, as the case may be, such determination is against Licensee, then such Product shall be deemed accepted by Licensee.

(c) Sole Remedy. Notwithstanding anything to the contrary in this Supply Agreement, the remedy set forth in this Section 2.5 will be Licensee's sole and exclusive remedy and recourse with respect to the shortages that are not also Stockout Periods, or nonconforming Product delivered to Licensee by Exelixis hereunder.

(d) Damage after Delivery. Licensee shall bear the risk of damage to the Product after delivery to Licensee pursuant to Section 2.3(c). If the Product is damaged after delivery to Licensee pursuant to Section 2.3(c) and Licensee intends to order replacement Product, Licensee shall promptly notify Exelixis of the damage and any orders for replacement Product, and Exelixis may, at its sole discretion but in good faith, accept or reject all or a portion of the order for the replacement Product.

2.6 Quality Agreement. The Parties have substantially agreed to the terms and conditions of a quality agreement (the "**Quality Agreement**") setting forth in detail the quality assurance arrangements and procedures for the Manufacture of the Product, which Quality Agreement will be in substantially the form attached hereto as Exhibit B and incorporated herein by reference. To the extent that the terms of this Supply Agreement and those of the Quality Agreement are in conflict, the terms of this Supply Agreement shall control except with respect to quality issues, which shall be governed by the Quality Agreement. For clarity, if there are any financial terms in the Quality Agreement that are in conflict with this Supply Agreement, this Supply Agreement shall control with respect to such financial terms.

2.7 Business Continuity Plan. Within [*] after Regulatory Approval, Exelixis and Licensee shall begin preparation of a business continuity plan that would address, as a result of a Force Majeure Event or otherwise, Exelixis' inability to provide the supply of Product or the volume of Product as forecasted, including a set of clearly defined measures that would allow a quick response and recovery to the disruption of Product supply. Specifically, such business continuity plan will address, at a minimum, provisions related to rolling safety stock, Exelixis' holdings of API stock, and Exelixis' holdings of sufficient API stock to cover the period necessary for a successful transfer to a new commercial manufacturer under Section 2.(e),

provisions for technology transfer of API and Product manufacturing capabilities if applicable in the event of a failure in performance of the then-current contract manufacturing organization. In addition, the Parties shall agree that in the event Licensee were to forecast that future sales of the Product shall exceed [*] in one Calendar Year, the business continuity plan shall be revised to include the set-up of a second manufacturing facility for the Finished Product. The Parties shall submit the business continuity plan to the JSC (or a manufacturing subcommittee) for further discussion. The Parties shall review the business continuity plan on a yearly basis (or at such other intervals as the Parties may agree).

2.8 Backup Supplier. In the event that for a period of [*], Exelixis has failed to supply at least [*] of the quantity of the Product set forth in the binding portion of the Order Forecast, upon Licensee's request, Exelixis shall select a Third Party manufacturer (a "**Backup Manufacturer**") that is reasonably acceptable to Licensee to Manufacture the Product for supply to Licensee to the extent Exelixis is unable to meet Licensee's requirement for the Product as set forth in the binding portion of the Order Forecast. The costs and expenses associated with the engagement of the Backup Manufacturer, including the costs for transferring the Manufacturing process to such Backup Manufacturer, shall be borne by Exelixis.

2.9 Allocation in the Event of Product Shortages.

(a) This Section 2.9 shall apply in the event that Exelixis is unable to supply, with respect to a Calendar Quarter, [*] of (i) Product ordered by Licensee pursuant to Sections 2.2 and 2.3 for delivery in such Calendar Quarter, plus (ii) Product required by Exelixis or its Affiliates or other licensees for their own use with respect to such Calendar Quarter (such event, a "**Shortfall**"). The purpose of these allocation rules is to permit Licensee (with respect to the Licensee Territory) and Exelixis (with respect to the Exelixis Territory) to independently make their respective long-term purchase decisions for the Product, with the benefits and risks of such purchase decisions to be allocated to Licensee or Exelixis, as the case may be.

(b) If Exelixis is unable to supply [*] of (i) Product ordered by Licensee pursuant to a Purchase Order plus (ii) Product required by Exelixis or its Affiliates or other licensees for their own use, then the available Product in each Calendar Quarter in which a Shortfall occurs shall be [*].

(c) The [*] set forth in this Section 2.9 shall restart for each Calendar Quarter, without any carryover of a Shortfall realized by either Licensee or Exelixis in the prior Calendar Quarter.

(d) If Exelixis determines that it will not be able to deliver the quantities of the Product specified in the Purchase Order on the requested delivery date, or Exelixis is made aware of any future anticipated shortages, then Exelixis shall promptly notify Licensee of such determination, and in any event, no later than [*] following such determination. Such notification shall include the reasons for and the expected duration of Exelixis' anticipated inability to deliver such quantities of the Product. Promptly thereafter, but in no event more than [*] after such notification, the Parties shall discuss in good faith the matters set forth in such notification and begin good faith negotiations with respect to an alternative delivery schedule or

alternative sourcing for such Product; *provided* that any such negotiations shall not relieve Exelixis of its obligations hereunder.

2.10 Continuous Improvement; Supply Contacts.

(a) The Parties acknowledge their common goal in optimizing the supply chain and reducing the costs associated with the Manufacturing and supply of the Product. As part of the supply chain optimization, the Parties shall cooperate to optimize, among others, an agreed-on service level measured by means of key performance indicators, as well as seek to extend the duration of the Product shelf life to at least [*]. The Parties will discuss cost reduction mechanisms through the JSC (or any manufacturing subcommittee established by the JSC). The Parties shall reasonably cooperate with each other to implement such improvement, the cost of which shall be shared by the Parties as mutually agreed.

(b) 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 Product 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 Product under this Agreement. Supply Contact shall have decision-making authority within the guidance and subject to the review and approval of the JSC. 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.

2.11 Stockout Period. In the event of a Stockout Period, Licensee shall be entitled to certain royalty reductions as provided under Sections 6.3(e) and 9.5(f) of the Collaboration and License Agreement. In addition to such royalty reductions, in the event that Exelixis recovers third party damages arising directly from a Stockout Period, Exelixis agrees to share such damages with Licensee [*] in accordance with each party's demonstrated losses.

ARTICLE 3
FINANCIALS

3.1 Price. The transfer price (the "**Transfer Price**") for Finished Product supplied by Exelixis to Licensee will be equal to [*], which shall be calculated for each configuration of the Product.

3.2 Invoice and Payment. Concurrently with delivery of Product to Licensee, Exelixis shall submit to Licensee an invoice for payment, in U.S. Dollars, of the Transfer Price for Product included in such delivery. Licensee shall pay each invoice, in U.S. Dollars, within [*] following the date of such invoice by wire transfer of immediately available funds into an account designated by Exelixis. Financial audits shall be conducted in accordance with Section 10.4 of the Collaboration and License Agreement, and late payments shall bear interest as set forth in Section 10.5 of the Collaboration and License Agreement.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

3.3 Other Manufacture Related Costs. Licensee shall be responsible for the costs and expenses of any Manufacture-related work that is performed by or on behalf of Exelixis at Licensee's reasonable request, which costs and expenses are not included in the calculation of COG. Within [*] after the end of each Calendar Quarter during which such work has been performed by or on behalf of Exelixis at Licensee's request, Exelixis shall submit to Licensee a reasonably detailed invoice, in U.S. Dollars, setting forth the costs and expenses incurred by Exelixis in connection with such work. Licensee shall pay to Exelixis the amount invoiced, in U.S. Dollars, within [*] after the receipt of the invoice by wire transfer of immediately available funds into an account designated by Exelixis. Late payments shall bear interest as set forth in Section 10.5 of the Collaboration and License Agreement.

3.4 Tax. Licensee shall pay any and all taxes (other than taxes based on Exelixis' income), duties, assessments, and other charges and expenses imposed by any Government Authority in connection with the supply and transfer of Product to Licensee. If a withholding or deduction obligation occurs, then the sum payable by Licensee (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 which it would have received had no such withholding or deduction occurred.

ARTICLE 4
REGULATORY

4.1 Regulatory Inspections. Exelixis shall cooperate with any inspection of its facilities by any Regulatory Authority overseeing the Manufacture of the Product for use in the Licensee Territory. Each Party shall notify the other Party of any such inspection and shall permit the other Party's representative to observe such inspection to the extent such inspection is scheduled at least [*] in advance and such observation is permitted by applicable Laws and any applicable agreement between Exelixis and a Third Party (such as a contract manufacturing organization) in the event such facility is owned and/or operated by such Third Party.

4.2 GMP, Quality Assurance and Other Audits. Licensee shall have the right to conduct cGMP, quality assurance, and other audits (e.g., Environment, Health & Safety) pursuant to the terms and conditions of the Quality Agreement, but subject to any applicable agreement between Exelixis and a Third Party (such as a contract manufacturing organization) in the event such facility is owned and/or operated by such Third Party.

4.3 Inquiries and Customer Complaints. Licensee shall comply with the Pharmacovigilance Agreement and Section 5.5 of the Collaboration and License Agreement with respect to all inquiries, complaints, and adverse events regarding the Products in the Licensee Territory.

4.4 Notification of Potential Recall; Recalls. Each Party will act in accordance with the notice requirements set forth in Sections 5.7 and 5.9 of the Collaboration and License Agreement. In the event that any Recall with respect to a Product is the direct result of a breach of any warranty of Exelixis set forth in Section 8.2 and is not the result of Licensee's, its Affiliates', or its sublicensees' transportation, storage, marketing, use, sale, or distribution of the

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Product, then Exelixis shall bear (and reimburse Licensee for) all of the costs and expenses of such Recall and the destruction of such Recalled Product. To the extent that the reason for any Recall with respect to the Product hereunder is in part the direct result of the breach of any warranty of Exelixis set forth in Section 8.2 and in part the result of Licensee's, its Affiliates', or its sublicensees' transportation, storage, marketing, use, sale, or distribution of the Product, then the expenses of such Recall shall be allocated in an equitable manner between the Parties.

4.5 Reach Registration. If the Product is or contains any substance which has to be registered under Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals ("**REACH**") (hereinafter referred to as a "Substance"), Exelixis shall ensure that such Substance will be pre-registered and registered in accordance with REACH at the (pre-) registration date set forth under REACH, provided that Licensee and/or its Affiliates do not qualify as an importer of such Substance under REACH. Upon request of Licensee, Exelixis shall immediately provide Licensee with proof of the (pre-) registration of the Substance, and shall immediately inform Licensee if it becomes aware that any Substance was not (pre-) registered in due time or if the (pre-) registration is cancelled. If Licensee and/or any of its Affiliates qualify as an importer of the Substance under REACH, Exelixis shall, upon request of Licensee, provide Licensee and/or its Affiliates immediately with all data and information that Licensee and/or its Affiliates require for (i) the assessment as to whether such Substance must be (pre-) registered, and (ii) the (pre-) registration under REACH. Licensee and its Affiliates shall be entitled to use such data and information to the extent required for the (pre-) registration of the Substance

ARTICLE 5
CONFIDENTIALITY

5.1 Confidentiality. Any and all Information disclosed by a Party to the other Party under this Supply Agreement shall be deemed Confidential Information of such Party under the Collaboration and License Agreement and subject to the confidentiality provisions set forth in Article 14 of the Collaboration and License Agreement.

ARTICLE 6
INTELLECTUAL PROPERTY

6.1 Intellectual Property. Any and all inventions, whether patentable or not and including all intellectual property rights therein, generated by either Party in the course of conducting their activities under this Supply Agreement shall be deemed to be generated under the Collaboration and License Agreement and subject to the rights and obligations of the Parties as set forth therein.

ARTICLE 7
FORCE MAJEURE

7.1 Force Majeure. Notwithstanding anything to the contrary in this Supply Agreement, both Parties shall be excused from the performance of their obligations under this Supply Agreement to the extent that (a) force majeure prevents such performance or, with

respect to Exelixis' supply obligations pursuant to Article 2, prevents the combined supply of (i) Product specified in accepted orders placed by Licensee in accordance with Section 2.3(a) and (ii) Product required by Exelixis and its Affiliates, and (b) the nonperforming Party promptly provides notice of the force majeure to the other Party. Such excuse shall continue so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Supply Agreement, force majeure shall include conditions beyond the reasonable control of the applicable Party, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm, or like catastrophe, and failure of plant or machinery. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than [*], then the Parties will discuss in good faith the modification of the Parties' obligations under this Supply Agreement in order to mitigate the delays caused by such force majeure.

ARTICLE 8
REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

(a) Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated.

(b) Corporate Power, Authority and Binding Agreement. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Supply Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Supply Agreement and the performance of its obligations hereunder; and (iii) this Supply Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, and similar Laws affecting creditors' rights and remedies generally.

8.2 Product Warranties. Exelixis represents and warrants to Licensee that:

(a) all Product supplied to Licensee pursuant to this Supply Agreement will be Manufactured in conformity with cGMPs and Good Distribution Practice;

(b) each Product supplied to Licensee pursuant to this Supply Agreement, at the time of shipment of such Product to Licensee pursuant to Section 2.3(c), will conform to the applicable Specifications for such Product; and

(c) all Product supplied to Licensee pursuant to this Supply Agreement will, at the time of shipment of such Product to Licensee pursuant to Section 2.3(c), be free and clear

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of all liens, security interests, and other encumbrances; provided, however, that Exelixis shall retain a security interest in such Product until Licensee pays for it in full pursuant to Section 3.2.

8.3 Disclaimers. EXCEPT AS EXPRESSLY STATED IN THIS SUPPLY AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, ARE MADE OR GIVEN BY OR ON BEHALF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Exelixis. Exelixis shall defend, indemnify, and hold the Licensee Indemnitees harmless from and against all Claims to the extent such Claims arise out of, are based on, or result from: (a) any negligence or willful misconduct of Exelixis, its Affiliates, or the officers, directors, employees, or agents of Exelixis or its Affiliates; or (b) Exelixis' breach of this Supply Agreement, including the representations and warranties contained herein. The foregoing indemnity obligations shall not apply to the extent that (i) the Licensee Indemnitees fail to comply with the indemnification procedure set forth in Section 9.3 and Exelixis' defense of the relevant Claims is prejudiced by such failure; or (ii) any Claim arises from, is based on, or results from any occurrence for which Licensee is obligated to indemnify the Exelixis Indemnitees under Section 9.2.

9.2 Indemnification by Licensee. Licensee shall defend, indemnify, and hold the Exelixis Indemnitees harmless from and against all Claims to the extent such Claims arise out of, are based on, or result from: (a) any negligence or willful misconduct of Licensee, its Affiliates, or the officers, directors, employees, or agents of Licensee or its Affiliates; (b) Licensee's breach of this Supply Agreement, including the representations and warranties contained herein; (c) the export, import, storage, packaging, or labeling, by or on behalf of Licensee or its Affiliates or sublicensees, of any Product supplied by Exelixis hereunder; or (d) the commercialization of any Product supplied by Exelixis hereunder. The foregoing indemnity obligations will not apply to the extent that (i) the Exelixis Indemnitees fail to comply with the indemnification procedure set forth in Section 9.3 and Licensee's defense of the relevant Claims is prejudiced by such failure; or (ii) any Claim arises from, is based on, or results from any activities or occurrence for which Exelixis is obligated to indemnify the Licensee Indemnitees under Section 9.1.

9.3 Indemnification Procedures. The Party claiming indemnity under this Article 9 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim and shall offer control of the defense of such Claim to the Indemnifying Party. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, that the Indemnifying Party shall have the right to assume and

conduct the defense of such Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 9.

9.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS SUPPLY AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 9.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTIONS 9.1 OR 9.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 5.

ARTICLE 10
TERM AND TERMINATION

10.1 Term. This Supply Agreement will become effective on the Effective Date and, unless earlier terminated pursuant to this Article 10, will remain in effect until the expiration of the Collaboration and License Agreement (the "**Term**").

10.2 Termination.

(a) Termination for Breach. A Party's material breach of this Supply Agreement will constitute such Party's material breach of the Collaboration and License Agreement, and each Party shall have the right to terminate this Supply Agreement and the Collaboration and License Agreement for the other Party's uncured material breach of this Supply Agreement as set forth in Section 15.2(a) of the Collaboration and License Agreement.

(b) Termination Due to Termination of the Collaboration and License Agreement. This Supply Agreement shall automatically terminate upon termination of the Collaboration and License Agreement.

10.3 Performance on Termination; Survival. Termination or expiration of this Supply Agreement shall not affect the rights or obligations of the Parties under this Supply Agreement that have accrued prior to the date of termination or expiration. Upon termination of this Supply Agreement for any reason: (a) Products Manufactured pursuant to Purchase Orders

will be delivered on the scheduled delivery dates and Licensee shall pay Exelixis not later than [*] after the delivery date (provided, however, that Licensee makes advance payment prior to shipment in the event of termination due to payment default by Licensee); and (b) all costs of unused raw materials, labels, and packaging incurred by Exelixis shall be paid by Licensee in the event that Exelixis terminates this Supply Agreement pursuant to Section 10.2(a) or that this Supply Agreement is terminated pursuant to Section 10.2(b) as a result of termination of the Collaboration and License Agreement by Licensee pursuant to Sections 15.3(a) or (b) of the Collaboration and License Agreement. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Supply Agreement: Sections 5, 6, 8, 9, 10.3 and 11.

ARTICLE 11
MISCELLANEOUS

11.1 Entire Agreement; Amendment. This Supply Agreement, including the Exhibits, together with the Collaboration and License Agreement, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to the subject matter hereof and supersedes all prior and contemporaneous agreements and communications, whether oral, written, or otherwise, with respect to the subject matter hereof. This Supply Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by an authorized officer of each Party. No modification to this Supply Agreement will be effected by the acknowledgment or acceptance of any Purchase Order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein.

11.2 Notices. Any notice to be given under this Supply Agreement must be in writing and specifically refer to this Supply Agreement, and be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party, and will be deemed to have been given for all purposes (a) when received, if hand-delivered; (b) if air mailed, five (5) days after the date of postmark; (c) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries; or (d) 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 Licensee, notices must be addressed to:

Ipsen Pharma SAS
65 Quai Georges Gorse
92100 Boulogne-Billancourt, France
Attention: Jonathan Barnsley, EVP Technical Operations
Facsimile: [*]

with a copy to:

Ipsen Pharma SAS
65 Quai Georges Gorse
92100 Boulogne-Billancourt, France

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Attention: François Garnier, EVP General Counsel
Facsimile: [*]

If to Exelixis, notices must be addressed to:

Exelixis, Inc.
210 East Grand Avenue
South San Francisco, CA 94080, USA
Attention: Executive Vice President and General Counsel
Facsimile: [*]

11.3 Interpretation. The headings of clauses contained in this Supply Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and do not constitute any part of this Supply Agreement, or have any effect on its interpretation or construction. All references in this Supply Agreement to the singular include the plural where applicable. Unless otherwise specified, references in this Supply Agreement to any Article include all Sections, subsections, and paragraphs in such Article, references to any Section include all subsections and paragraphs in such Section, and references in this Supply Agreement to any subsection 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 Supply Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Supply Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Supply 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 Supply Agreement has been prepared in the English language and the English language controls 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 Supply Agreement shall be in the English language.

11.4 Assignment. Except as expressly provided hereunder, neither this Supply 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 assignment of the Collaboration and License Agreement to a Third Party as set forth in Section 17.5 of the Collaboration and License Agreement; 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 Supply 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 11.4. Any assignment not in accordance with this Section 11.4 shall be null and void.

11.5 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Supply Agreement, and shall cause its Affiliates to comply with the provisions of this Supply Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Supply Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

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

11.7 Severability. If, for any reason, any part of this Supply Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions will remain in full force and effect as if the original Supply Agreement had been executed without the invalidated, unenforceable, or illegal part.

11.8 No Waiver. The failure of a Party to insist upon strict performance of any provision of this Supply Agreement or to exercise any right arising out of this Supply Agreement will neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

11.9 Relationship Between the Parties. The Parties' relationship, as established by this Supply Agreement together with the Collaboration and License 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.

11.10 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.

11.11 Governing Law; Dispute Resolution. This Supply Agreement, and all questions regarding the existence, validity, interpretation, breach, or performance of this Supply Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles. The application of the U.N. Convention on Contracts for the International Sale of Goods (1980) is excluded. Any controversy or

claim arising out of, relating to, or in connection with any provision of this Supply Agreement shall be resolved in accordance with Article 16 of the Collaboration and License Agreement.

11.12 Compliance with Laws. Each Party shall comply in all material respects with all applicable Laws and regulations, including, but not limited to, those concerning drugs, drug manufacture regulatory requirements, or exportation or importation of Products, including but not limited to proper declaration of dutiable values. Except as provided in Section 2.3(c), Licensee shall be responsible for obtaining all exportation and importation licenses or other authorizations.

11.13 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 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 services to be performed under this Supply Agreement. 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.

{SIGNATURE PAGE FOLLOWS}

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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

EXELIXIS, INC.	**IPSEN PHARMA SAS**
By: /s/ Michael M. Morrissey	By: /s/ Marc de Garidel
Name: Michael M. Morrissey	Name: Marc de Garidel
Title: CEO	Title: Chairman & CEO

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

LIST OF EXHIBITS

Exhibit A: Form of Order Forecast

Exhibit B: Quality Agreement

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Exhibit A
Form of Order Forecast

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit B
Quality Agreement

COMMERCIAL QUALITY TECHNICAL AGREEMENT

Between the CONTRACT GIVER
hereinafter called

EXELIXIS Inc.

and the CONTRACT ACCEPTOR
hereinafter called
Ipsen

TABLE OF CONTENTS

1.0 SCOPE

1.1 The commercial arrangements relating to the *development and commercialization of cabozantinib outside the U.S., Canada and Japan* shall be dealt with in a separate Supply Agreement (the "Supply Agreement") between EXELIXIS and Ipsen.

1.2 This commercial Quality Technical Agreement (the "Quality Technical Agreement") is a required and integral part of the Supply Agreement. This Quality Technical Agreement defines the responsibilities related to quality systems and GMP and GDP requirements for the development and commercialization of Drug Substance and Product. Duties and responsibilities are defined in detail as required in the US GMP Code of Federal Regulations and European regulations.

1.3 All initially capitalized terms used herein and not otherwise defined herein shall have the meanings set forth in the Supply Agreement. In the event of any inconsistency between the provisions of this Quality Technical Agreement and the terms and conditions of the Supply Agreement, the terms and conditions of the Supply agreement shall prevail (except that the Quality Technical Agreement shall prevail in the consideration of Quality and GMP/GDP Matters, including without limitation matters relating to quality control and testing).

1.4 The appendices and enclosures to this Quality Technical Agreement are an integral part of the Quality Technical Agreement and are incorporated into this Quality Technical Agreement by such reference.

1.5 In this Quality Technical Agreement, "authorization," "approval", "in writing" and "written communication" shall mean on official letterhead or approved forms and signed by the authoring party's Quality Assurance (QA) representative. Transmission of such written documentation may be by mail, courier or a scan (.pdf) attached to an email.

1.6 Tthis Quality Technical Agreement is made between:

EXELIXIS, Inc.
210 East Grand Avenue
South San Francisco CA 94080
USA
Referred to as EXELIXIS in this Quality Technical Agreement,

And

Ipsen Pharma SAS
65 Quai Georges Gorse
92100 Boulogne-Billancourt
France
Referred to as Ipsen in this Quality Technical Agreement.

For clarity, in this Quality Technical Agreement, “Ipsen” and “Ipsen Territory” shall have the same meaning as “Licensee” and “Licensee Territory”, respectively, in the Supply Agreement.

2.0 AUTHORIZATIONS

2.1 Manufacturing License

2.1.1 Once EXELIXIS has been made aware of Ipsen’s proposed regulatory filings, and with sufficient notice, EXELIXIS shall ensure that the contract manufacturers used to produce Product have all necessary licenses to produce the Product for distribution in Ipsen Territory as mutually agreed.

2.2 Product License

2.2.1 EXELIXIS shall be responsible for applying and obtaining approval for the initial new drug application for the Product and for any supplements thereto in the U.S., Canada and Japan (collectively, the “NDA”).

2.2.2 EXELIXIS has filed the initial Marketing Authorization Application (MAA) for approval in Europe for the Product and the Ipsen shall be responsible for any other filings, variations or supplements and obtaining approvals in Ipsen Territory. At such time that Ipsen makes the idecision to file a regulatory application, Ipsen shall, with sufficient notice, notify EXELIXIS of any regulatory requirements as a result of the potential application, where EXELIXIS may be required to prepare additional information.

3.0 DURATION OF AGREEMENT, REVIEW AND CHANGES

3.1 This Quality Technical Agreement shall be effective as of the last date all required signatures are appended below, and shall expire at the termination of the Supply Agreement for the Product.

3.2 Changes or supplements to this Quality Technical Agreement or to the Appendices and Enclosures can only be made by mutual consent of EXELIXIS and Ipsen in writing. Such changes shall be recorded, approved and filed in the Change History Log (Appendix I) with each subsequent revision. The appendices and enclosures to this Quality Technical Agreement are part of the Quality Technical Agreement.

3.2.1 [*].

4.0 COMPLIANCE

4.1 [*].

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.0 QUALITY SYSTEMS

5.1 Quality Responsibilities

5.1.1 EXELIXIS shall ensure that the level of quality determined by GMP is maintained throughout the manufacturing, packaging and labeling processes.

5.1.2 EXELIXIS shall ensure that the level of quality determined by GMP and GDP is maintained throughout manufacturing, testing and the distribution network as set forth in the Commission Guidelines 2013/C 343/01 and any and all related Directives and applicable regulatory requirements, as may be amended from time to time.

5.1.3 Ipsen and EXELIXIS shall each be responsible for:

5.1.3.1 Approving the Quality Technical Agreement,

5.1.3.2 Ensuring that the terms of this Quality Technical Agreement are complied with,

5.1.3.3 Ensuring that the terms of this Quality Technical Agreement are performed in accordance with cGMPs, GDPs and applicable ICH Guidelines.

5.2 Personnel and Management Responsibility

5.2.1 Ipsen and EXELIXIS shall notify the corresponding Quality Assurance group of any relevant Quality organizational changes.

5.2.2 Ipsen and EXELIXIS shall have a training system for assuring personnel dealing with overseeing manufacturing, packaging, development and commercialization activities are trained for their job function.

5.3 Document Retention

5.3.1 [*].

5.4 Drug Substance Production

5.4.1 [*].

5.4.2 [*].

5.5 Drug Product Production

5.5.1 [*].

5.5.2 [*].

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

5.6 Release of Product – Ipsen Territory.

5.6.1 For supplies going to the Ipsen Territory, the following shall apply:

5.6.1.1 [*]:

- [*].
- [*].
- [*].
- [*].
- [*].

5.6.1.2 EXELIXIS has sole authority to release the material for use in the U.S., Canada and Japan.

5.6.1.3 [*].

5.7 Post Release Issues and Product Complaints

5.7.1 Ipsen shall comply with the Pharmacovigilance Agreement of the Collaboration and License Agreement once finalized with respect to all inquiries, complaints, and adverse events regarding the Products in the Ipsen Territory.

5.7.2 EXELIXIS and Ipsen shall maintain systems for resolving all customer complaints, adverse events, and inquiries related to the Product.

5.7.3 [*].

5.7.4 [*].

5.7.5 [*].

5.7.6 [*].

5.7.7 It is expected that most customer complaints, adverse events, and inquiries for the Product shall be received by EXELIXIS for the U.S., Canada, and Japan and by Ipsen for Ipsen Territory.

5.7.8 [*].

5.7.8.1 [*].

5.8 Product Recall and Returns

5.8.1. Based on initial non-conformance information, both Parties will jointly determine if an investigation is required.

5.8.2 [*].

5.8.3 [*]. Ipsen shall comply with all Regulatory Authority requirements.

5.8.4 [*]. EXELIXIS shall comply with all Regulatory Authority requirements.

5.8.5 [*]. [*] shall support any recall decision and effort [*]]

5.8.6 [*] shall be responsible for the destruction of returned Product [*]. . [*].

5.9 Change Control

5.9.1 [*] to ensure appropriate review of regulatory changes [*].

5.10 Annual Product Quality Reviews

5.10.1 [*] shall be responsible for preparing an Annual Product Quality Review (APQR) for [*];

5.10.2 [*] shall be responsible for preparing an [*] Annual Product Quality Review (APQR) for [*].

5.10.3 The data for the APQR shall be provided by [*].

5.10.4 A standardized format and content shall be agreed upon by both parties.

5.10.5 The APQR shall include all Manufacturing, storage, testing and release activities, as well as additional applicable requirements in Ipsen Territory as amended from time to time, conducted by EXELIXIS' contract manufacturer's for a given time period. The APQR data shall include but is not limited to:

- Analytical Request Forms
- Batches manufactured and disposition status (including dates of manufacture)
- Summary of Drug Substance test results (including manufacturer lot number)
- QC testing trends and data: In-Process, COA, Analytical Report Form (ARF), Stability
- Product complaints, recalls, returns and any salvages as applicable.
- Summary of any production changes at EXELIXIS' contract manufacturer in the Manufacturing, testing, storage, validation, and

release process of the bulk Drug Substance, Product and Finished Goods.

- Summary of all deviations, deviation trend results, and associated corrective actions for the bulk Drug Substance, Product and Finished Product.
- Summary of CAPAs associated with significant deviations, investigations and trends and the status of those CAPAs at close of the APQR period for the bulk Drug Substance, Product and Finished Product.
- Status of recommendations from the previous Product APQR and status of corrective actions which were in an open status at the time of the previous APQR.

6.0 DRUG PRODUCTION CONTROL

6.1 Deviations

6.1.1 Ipsen and EXELIXIS shall utilize their Deviation procedure/systems to ensure appropriate review of all Product events. A Deviation is an event in the manufacturing process and/or support system that are outside of approved operating parameters, approved procedures, approved Specifications, or a departure from accepted GMPs.

6.1.2 [*] shall [*] inform [*].

7.0 COMPONENTS AND RAW MATERIALS

7.1 Audits of **COMPONENT AND RAW MATERIAL** Suppliers

7.1.1 EXELIXIS shall perform, or arrange to have performed, audits or GMP evaluations as applicable of suppliers of components purchased by EXELIXIS and its contract manufacturers to ensure the proper manufacturing and handling of materials and to ensure appropriate quality systems are in place. If requested by Ipsen, EXELIXIS shall request from its suppliers permission to allow Ipsen to review EXELIXIS audit reports at Exelixis's discretion and within reasonable limitations,

7.2 Retain/Reserve Samples

7.2.1 [*] shall be responsible for [*].

7.2.2 [*] shall store [*].

8.0 WAREHOUSING

8.1 EXELIXIS shall store and ship Product in accordance with GMP, GDP and approved Drug Substance and Drug Product storage and shipping requirements, specifications and procedures.

9.0 QUALITY CONTROL (QC) AND TESTING

9.1 [*]:

9.1.1 [*].

9.2 [*].

9.3 [*].

9.4 Out of Specification (OOS) Investigations

9.4.1 [*].

9.4.2 [*].

[*].

9.5 Stability

9.5.1 [*].

9.5.2 [*] shall have the responsibility of [*].

9.5.3 For the Ipsen Territory stability program; [*].

9.5.4 Should specific territory tests be required, [*].

10.0 QUALITY VISITS, GMP COMMISSIOINING, AND AUDITS

10.1 Compliance Audits

10.1.1 [*].

11.0 INSPECTIONS BY REGULATORY AGENCIES

11.1 [*].

11.2 [*].

12.0 CHANNELS OF COMMUNICATION

12.1 EXELIXIS and Ipsen have designated Quality representatives to oversee the respective obligations in the functions regarding the Product and the Quality Technical Agreement.

12.2 Any Quality issue that cannot be resolved through the normal communication channels such as e-mail, phone calls, and team meetings/teleconferences shall be escalated to the Supply Contacts for both parties and the JSC [*].

12.3 Should the impasse not be resolved at the senior management level, further issue escalation may involve executive management at both EXELIXIS and Ipsen.

12.4 Ipsen and EXELIXIS Quality Assurance shall review this Quality Technical Agreement in 2018 and make necessary amendments [*]. After 2018, EXELIXIS and Ipsen shall review this Quality Technical Agreement biennially and make any necessary revisions. This review and any resulting revisions shall be documented in the Change History Log (Appendix I).

13.0 Product Shortage

13.1 EXELIXIS shall notify the applicable Regulatory Agency in the US, Canada and Japan of potential or known shortages in accordance with applicable regulations and regulatory expectations in those territories.

13.2 Ipsen shall notify the applicable Regulatory Agency in the Ipsen Territory of potential or known shortages in accordance with applicable regulations and regulatory expectations in those territories.

14.0 APPROVAL OF QUALITY TECHNICAL AGREEMENT

Signed for an on behalf of	Signed for and on behalf of
EXELIXIS	IPSEN
Gisela Schwab	Chris Masterson
President & Chief Medical Officer	Senior Vice President, Quality

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

APPENDIX I - CHANGE HISTORY LOG

Upon revision of this Quality Technical Agreement or any Appendix to this Quality Technical Agreement, this Change History Log shall be updated. The Change History Log shall be maintained by EXELIXIS. It is the responsibility of each document holder to replace the superseded revision with the revised approved revision. Superseded copies may be retained for historical records, but must be marked to appropriately indicate the historical status of the document.

Annual reviews of this Quality Technical Agreement and appendices, not resulting in a revision to the document, shall be documented as a review and signed on the Change History Log.

It is each party's responsibility to ensure that staff is adequately informed and any procedural or documentary changes resulting from a revision are implemented in the areas affected by the changes.

[*]

APPENDIX II – CONTACTS

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.6

FIRST AMENDMENT TO SUPPLY AGREEMENT

This **FIRST AMENDMENT TO THE SUPPLY AGREEMENT** (the "**Amendment**") is entered into as of October 26, 2017 (the "**Amendment 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 **Ipsen Pharma SAS**, a French corporation having an address at 65 Quai Georges Gorse, 92100 Boulogne-Billancourt, France ("**Licensee**"). Exelixis and Licensee may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

RECITALS

WHEREAS, Exelixis and Licensee are parties to that certain Collaboration and License Agreement dated February 29, 2016, as amended by Amendment No. 1 dated effective December 20, 2016, Amendment No. 2 dated effective September 14, 2017, and Amendment No. 3 dated effective October 26, 2017 (together, the "**License Agreement**"), pursuant to which the Parties have been collaborating on the development and commercialization of cabozantinib; and

WHEREAS, Exelixis and Licensee are parties to that certain Supply Agreement dated February 29, 2016, as amended by that certain Side Letter between the Parties dated August 26, 2016 (together, the "**Supply Agreement**"), pursuant to which Exelixis has been manufacturing and supplying cabozantinib to Licensee for development and commercial use under the License Agreement; and

WHEREAS, the Parties desire to enter into this Amendment to amend the Supply Agreement to reflect the expansion of Licensee's territory under the License Agreement,remove reference to the concept of a transition plan transferring manufacturing obligations to Licensee, and make certain other changes, all on the terms and conditions set forth below.

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

1. DEFINITIONS

1.1 The fourth sentence of Section 1.7 of the Supply Agreement ("Cost of Goods" or "COG") is hereby amended and restated to read as follows:

"Direct labor costs shall include the cost of: [*]"

1.2 Section 1.11 of the Supply Agreement is hereby amended and restated to read in full as follows:

"**1.11** "**Exelixis Territory**" means the U.S. and Japan."

1.3 Section 1.23 of the Supply Agreement is hereby amended and restated to read in full as follows:

"1.23 "**Manufacture**" means all activities related to the manufacturing of the Compound and Products, in final, labeled, packaged form for commercial use, including in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, ongoing stability tests and regulatory activities related to any of the foregoing. "**Manufacturing**" has a correlative meaning."

1.4 Section 1.25 of the Supply Agreement ("Product") is hereby amended and restated to read as follows:

"**1.25**. **Product**" means any pharmaceutical product containing the Compound as an active ingredient, in any form, presentations, dosage, or formulation. For the avoidance of doubt, the manufacturing and supply of product bearing the trade name Cometriq® shall be covered under a separate agreement entered into between the Parties on November 21, 2016.

1.5 Section 1.30 of the License Agreement is hereby amended and restated to read in full as follows:

"**1.30 "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, the EMA, and Health Canada or other foreign equivalent. For countries where governmental approval is required for pricing or reimbursement for a pharmaceutical product to be reimbursed by national health insurance (or its local equivalent), Regulatory Authority shall also include any Governmental Authority whose review or approval of pricing or reimbursement of such product is required."

1.6 [*]

1.7 "**Health Canada**" means the federal department of the government of Canada having the authority to regulate the sale of medicinal or pharmaceutical products, or any successor agency thereof.

1.8 "**RoW Countries**" or Rest of the World Countries, means all of the other countries of the world except [*].

1.9 Unless otherwise defined in this Amendment, all capitalized terms have the meaning as defined in the Supply Agreement.

2. PRODUCT SUPPLY

2.1 Section 2.3(c) of the Supply Agreement is hereby amended and restated to read in full as follows:

"2.3(c) Delivery and Shipping Terms. Purchase Orders submitted for quantities of Product that are in accordance with Section 2.3(a) and/or Section 2.3(b) will be binding on both Parties after acceptance in writing by Exelixis; provided, however, that should Exelixis neither reject a Purchase Order nor provide written confirmation of acceptance within [*] of receipt, Exelixis shall be deemed to have accepted the Purchase Order effectively. The Purchase Order will specify a single delivery date for such order to be delivered in such Calendar Quarter, but will in no event be a date sooner than [*]. By way of example, a Purchase Order submitted on [*] would specify the quantity of Product ordered for delivery in the [*] Calendar Quarter of [*], with a delivery date no sooner than [*]. Licensee shall place Purchase Orders of desired quantity of Products labeled for commercial use in Canada for delivery by Exelixis in Canada, [*]. With respect to Products labelled for commercial use in countries of the Licensee Territory other than Canada, a separate Purchase Order shall be placed and Exelixis shall deliver all Products [*] once the Finished Products are released by Exelixis or through its contract manufacturer as described in Section 2.4(d) below. Exelixis shall be responsible for obtaining all licenses or other authorizations for the exportation of such shipments and shall supply Licensee with the documentation required for filing or claiming credit or deduction for any applicable taxes and/or duties. Licensee shall be responsible for obtaining all freight, handling, insurance, and shipping expenses for shipments upon and after unloading at the [*], and shall be the importer of record and responsible for all duties and taxes for such importation in the Licensee Territory, and shall be responsible for obtaining all distribution licenses for the Products."

2.2 Section 2.4(e) of the Supply Agreement is hereby deleted in its entirety.

2.3 Section 2.8 of the Supply Agreement is hereby deleted in its entirety and replaced in full to read as follows

"2.8 Backup Supplier. Exelixis shall select a Third Party secondary manufacturer (a "**Backup Manufacturer**") to Manufacture the Product for supply to Licensee. Exelixis shall engage the Backup Manufacturer, and complete, on or before the [*], to the reasonable satisfaction of Licensee, the transferring of the Manufacturing process to such Backup Manufacturer, qualification of the Backup Manufacturer, equipment and all validation of Manufacturing process in accordance with applicable law and regulations. At Ipsen's request, Exelixis shall also assist Ipsen in its applications for Regulatory Approval of the Backup Supplier by the relevant Regulatory Authorities of the Major Market Countries, to the extent commercially reasonable, and in accordance with Ipsen's timelines."

2.4. The following is hereby added to the Supply Agreement as Section 2.12:

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

“2.12 Canada-Labeled Product Reporting. On a [*] basis, Licensee shall provide to Exelixis a report, in a form to be mutually agreed by the Parties, which specifies in reasonable detail the distribution and/or sale of Product labeled for Canada by Licensee, its Affiliates, its permitted Sublicensees, and/or any Third Party distributors in the previous [*].”

3. FINANCIALS

3.1 Section 3.1 of the Supply Agreement is hereby amended and restated to read in full as follows:

“**3.1. Price.**

(a) The transfer price (the “**Transfer Price**”) for Finished Product supplied by Exelixis to Licensee will be equal to [*], which shall be calculated for each configuration of the Product. The Transfer Price in effect at the time the first Purchase Order is placed as part of the binding commitment under Section 2.2(b) shall apply as the Transfer Price for the Calendar Year. The Transfer Price shall thereafter be calculated and adjusted annually in the manner set forth in paragraph (b) below.

(b) [*] Reconciliation. On or prior to [*] of a Calendar Year, Exelixis and Licensee shall review the Transfer Price paid by Licensee for the Finished Product supplied during the preceding Calendar Year and determine if the [*] is either lesser or greater than the Transfer Price paid by Licensee during such preceding Calendar Year (the “[*] **Reconciliation**”). If the Transfer Price paid by Licensee during the preceding Calendar Year is less than the [*] owed to Exelixis, Licensee shall pay the difference for such amounts. If the Transfer Price paid by Licensee for the Product is greater than the [*] owed to Exelixis, Exelixis shall credit the amount of such payment due by Licensee to Exelixis until such time that the reconciling payment has been fully credited to Licensee.

(c) Adjustments to Transfer Price. On or prior to [*] of a Calendar Year at the time of the [*] Reconciliation, Exelixis and Licensee shall review the most recent Order Forecast provided by Licensee, and based on quantities planned for purchase and expected annual price increases by Exelixis’ Third Party manufacturers, and other related price factors, Exelixis and Licensee shall agree upon a new annual Transfer Price for the Calendar Year. The Parties agree that if by [*] of an applicable Calendar Year the Parties cannot agree on a new annual Transfer Price, the prior Calendar Year’s Transfer Price will apply, and any additional payments owed will be remediated through the next annual reconciliation in accordance with Section 3.1(b) above.”

3.2 Section 3.3 of the Supply Agreement is hereby amended to add the following:

“FTEs dedicated to other Manufacture-related work and billed to Licensee under this Section 3.3, such FTEs shall be billed [*]. With respect to any Manufacture-related work that is specifically related to support Licensee’s: (i) [*] in RoW Countries of the

Licensee Territory and (ii) [*] in RoW Countries of the Licensee Territory, the Parties agree that Exelixis' direct labor costs of personnel to be engaged in such activities shall be capped [*]. If Exelixis, acting reasonably, considers that Manufacture-related work mentioned in the preceding sentence would require additional FTEs, Exelixis shall notify Licensee and the Parties shall agree in good faith as to the reasonable out-of-pocket costs in excess of [*] incurred during the conduct of such Manufacture-related work for the purpose of this Section 3.3."

4. EXHIBIT B – QUALITY AGREEMENT

4.1 Section 12.4 of the Quality Agreement set forth in Exhibit B is hereby amended and restated to read in full as follows:

"**12.4** Ipsen and EXELIXIS Quality Assurance shall review this Quality Technical Agreement in 2018 and make necessary amendments. After 2018, EXELIXIS and Ipsen shall review this Quality Technical Agreement [*] and make any necessary revisions. This review and any resulting revisions shall be documented in the Change History Log (Appendix I)."

5. GENERAL PROVISIONS

5.1 Effect of Amendment. Except as expressly modified herein, all terms and conditions set forth in the Supply Agreement, as in effect on the Amendment Effective Date, shall remain in full force and effect.

5.2 Entire Agreement. The Supply Agreement as modified by this Amendment, and together with the License Agreement, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to its subject matter. They supersede all prior and contemporaneous agreements and communications, whether written or oral, of the Parties regarding this subject matter.

5.3 Severability. If, for any reason, any part of this Amendment is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Amendment. All remaining portions shall remain in full force and effect as if the original Amendment had been executed without the invalidated, unenforceable, or illegal part.

5.4 Counterparts; Electronic or Facsimile Signatures. This Amendment 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 Amendment 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}

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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

EXELIXIS, INC.	IPSEN PHARMA S.A.S
By: /s/ Michael M. Morrissey	By: /s/ Christophe Jean
Name: Michael M. Morrissey, Ph.D.	Name: Christophe Jean
Title: President and CEO	Title: EVP Corporate Strategy & Business Development

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
EXCHANGE ACT RULES 13a-14(a) and 15d-14(a),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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, Ph.D.

Michael M. Morrissey, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 6, 2021

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
EXCHANGE ACT RULES 13a-14(a) and 15d-14(a),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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 6, 2021

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 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 April 2, 2021, to which this Certification is attached as Exhibit 32.1 (the "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 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 6th day of May 2021.

/s/ Michael M. Morrissey, Ph.D.
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)