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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 1, 2022
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 May 2, 2022, there were 320,740,721 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, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 723,269	$ 647,169
Short-term investments	847,060	819,905
Trade receivables, net	190,614	282,650
Inventory	28,467	27,493
Prepaid expenses and other current assets	53,333	57,530
Total current assets	1,842,743	1,834,747
Long-term investments	404,535	371,112
Property and equipment, net	106,169	104,031
Deferred tax assets, net	98,001	111,663
Goodwill	63,684	63,684
Other long-term assets	138,986	131,002
Total assets	$ 2,654,118	$ 2,616,239
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 17,285	$ 24,258
Accrued compensation and benefits	42,768	61,969
Accrued clinical trial liabilities	82,885	77,544
Rebates and fees due to customers	49,997	33,700
Accrued collaboration liabilities	32,492	86,753
Other current liabilities	63,652	53,366
Total current liabilities	289,079	337,590
Long-term portion of deferred revenues	8,035	8,739
Long-term portion of operating lease liabilities	50,636	51,272
Other long-term liabilities	12,517	8,023
Total liabilities	360,267	405,624
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: 320,268 and 318,842 at March 31, 2022, and December 31, 2021, respectively	320	319
Additional paid-in capital	2,448,130	2,427,561
Accumulated other comprehensive loss	(6,665)	(758)
Accumulated deficit	(147,934)	(216,507)
Total stockholders' equity	2,293,851	2,210,615
Total liabilities and stockholders' equity	$ 2,654,118	$ 2,616,239

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,	
	2022	**2021**
Revenues:		
Net product revenues	$ 310,298	$ 227,212
License revenues	32,067	27,528
Collaboration services revenues	13,615	15,490
Total revenues	355,980	270,230
Operating expenses:		
Cost of goods sold	13,203	13,198
Research and development	156,671	159,288
Selling, general and administrative	102,863	102,351
Total operating expenses	272,737	274,837
Income (loss) from operations	83,243	(4,607)
Interest income	1,822	2,682
Other income (expense), net	164	(90)
Income (loss) before income taxes	85,229	(2,015)
Provision for (benefit from) income taxes	16,656	(3,616)
Net income	$ 68,573	$ 1,601
Net income per share:		
Basic	$ 0.21	$ 0.01
Diluted	$ 0.21	$ 0.00
Weighted-average common shares outstanding:		
Basic	319,582	312,473
Diluted	323,289	321,287

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,	
	2022	**2021**
Net income	$ 68,573	$ 1,601
Other comprehensive loss:		
Net unrealized losses on available-for-sale debt securities, net of tax impact of $1,656 and $499	(5,907)	(1,736)
Comprehensive income (loss)	$ 62,666	$ (135)

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, 2022					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	318,842	$ 319	$2,427,561	$ (758)	$ (216,507)	$ 2,210,615
Net income	—	—	—	—	68,573	68,573
Other comprehensive loss	—	—	—	(5,907)	—	(5,907)
Issuance of common stock under equity incentive plans	1,426	1	5,512	—	—	5,513
Stock transactions associated with taxes withheld on equity awards	—	—	(4,960)	—	—	(4,960)
Stock-based compensation	—	—	20,017	—	—	20,017
Balance at March 31, 2022	320,268	$ 320	$2,448,130	$ (6,665)	$ (147,934)	$ 2,293,851

	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

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,	
	2022	**2021**
Net income	$ 68,573	$ 1,601
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	4,490	3,227
Stock-based compensation	19,759	34,653
Non-cash lease expense	1,385	1,221
Deferred taxes	15,318	(3,388)
Other, net	1,580	6,578
Changes in operating assets and liabilities:		
Trade receivables, net	91,793	(17,690)
Inventory	(3,520)	(2,090)
Prepaid expenses and other assets	(3,605)	1,872
Deferred revenue	(1,169)	13,422
Accrued collaboration liabilities	(54,261)	1,005
Accounts payable and other liabilities	7,376	(867)
Net cash provided by operating activities	147,719	39,544
Cash flows from investing activities:		
Purchases of property, equipment and other	(5,609)	(13,557)
Purchases of investments	(336,545)	(331,612)
Proceeds from maturities and sales of investments	267,615	407,424
Net cash (used in) provided by investing activities	(74,539)	62,255
Cash flows from financing activities:		
Proceeds from issuance of common stock under equity incentive plans	4,891	2,791
Taxes paid related to net share settlement of equity awards	(4,686)	(5,441)
Net cash provided by (used in) financing activities	205	(2,650)
Net increase in cash, cash equivalents, and restricted cash equivalents	73,385	99,149
Cash, cash equivalents and restricted cash equivalents at beginning of period	663,891	320,772
Cash, cash equivalents and restricted cash equivalents at end of period	$ 737,276	$ 419,921

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 patients with difficult-to-treat cancers. Using our considerable drug discovery, development and commercialization resources and capabilities, we have invented and brought to market innovative therapies that appropriately balance patient benefits and risks; we will continue to build on this foundation as we strive to provide cancer patients with new treatment options that improve upon current standards of care.

Today, four products that originated in Exelixis laboratories are available to be prescribed to patients. Sales related to our flagship molecule, cabozantinib, account for the large majority of our revenues. Cabozantinib is an inhibitor of multiple tyrosine kinases including MET, AXL, VEGF receptors and RET and has been approved by the U.S. Food and Drug Administration (FDA) and in 61 other countries as: CABOMETYX® (cabozantinib) tablets approved for advanced renal cell carcinoma (RCC), both alone and in combination with Bristol-Myers Squibb Company's (BMS) OPDIVO® (nivolumab), for previously treated hepatocellular carcinoma (HCC) and, currently by the FDA and the European Commission (EC), for previously treated, radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC); and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer (MTC). For physicians treating these types of cancer, cabozantinib has become or is becoming an important medicine in their selection of effective therapies.

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).

Our plan is to utilize our operating cash flows and cash and investments to expand the cabozantinib franchise by potentially adding new indications in areas of unmet medical need. We will also leverage our operating cash flows to continue advancing our diverse small molecule and biotherapeutics programs, exploring multiple modalities and mechanisms of action to discover new oncology drugs.

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, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022 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 fiscal year ended December 31, 2021, included in Part II, Item 8 of our Annual Report on Form 10-K filed with the SEC on February 18, 2022.

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2022, which is a 52-week fiscal year, will end on December 30, 2022 and fiscal year 2021, which was a 52-week fiscal year, ended on December 31, 2021. For convenience, references in this report as of and for the three months ended April 1, 2022 and April 2, 2021, and as of and for the fiscal year ending December 30, 2022 are indicated as being as of and for the three months ended March 31, 2022 and March 31, 2021, and the year ending December 31, 2022, 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

There have been no material changes to our significant accounting policies during the three months ended March 31, 2022, compared to the significant accounting policies disclosed in “Note 1. Organization and Summary of Significant Accounting Policies” of the “Notes to Consolidated Financial Statements” included in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Recently Adopted Accounting Pronouncements

There were no new accounting pronouncements adopted by us since our filing of the Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which could have a significant effect on our 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 fiscal year ended December 31, 2021, 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,	
	2022	2021
Product revenues:		
Gross product revenues	$ 448,237	$ 314,205
Discounts and allowances	(137,939)	(86,993)
Net product revenues	310,298	227,212
Collaboration revenues:		
License revenues	32,067	27,528
Collaboration services revenues	13,615	15,490
Total collaboration revenues	45,682	43,018
Total revenues	$ 355,980	$ 270,230

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,	
	2022	2021
Affiliates of McKesson Corporation	19 %	13 %
Affiliates of CVS Health Corporation	17 %	15 %
Affiliates of AmerisourceBergen Corporation	17 %	14 %
Ipsen Pharma SAS	10 %	13 %
Affiliates of Optum Specialty Pharmacy	10 %	9 %

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

	March 31, 2022	December 31, 2021
Affiliates of McKesson Corporation	22 %	10 %
Ipsen Pharma SAS	21 %	50 %
Affiliates of AmerisourceBergen Corporation	21 %	11 %
Affiliates of CVS Health Corporation	15 %	9 %

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

	Three Months Ended March 31,	
	2022	2021
U.S.	$ 314,065	$ 229,957
Europe	34,527	33,806
Japan	7,388	6,467
Total revenues	$ 355,980	$ 270,230

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 milestone 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 on sales of products containing cabozantinib by our collaboration partners.

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

	Three Months Ended March 31,	
	2022	2021
CABOMETYX	$ 302,812	$ 223,595
COMETRIQ	7,486	3,617
Net product revenues	$ 310,298	$ 227,212

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, 2021	$ 14,625	$ 8,875	$ 24,825	$ 48,325
Provision related to sales made in:				
Current period	86,620	12,087	38,734	137,441
Prior periods	154	(43)	387	498
Payments and customer credits issued	(83,004)	(10,227)	(24,641)	(117,872)
Balance at March 31, 2022	$ 18,395	$ 10,692	$ 39,305	$ 68,392

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 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 are primarily related to Ipsen Pharma SAS (Ipsen) and contract liabilities are primarily related to deferred revenues from Takeda Pharmaceutical Company Limited (Takeda).

Contract assets and liabilities were as follows (in thousands):

	March 31, 2022	December 31, 2021
Contract assets [1]	$ 3,235	$ 1,665
Contract liabilities:		
Current portion [2]	$ 7,349	$ 7,814
Long-term portion [3]	8,035	8,739
Total contract liabilities	$ 15,384	$ 16,553

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

During the three months ended March 31, 2022, and 2021, we recognized $2.4 million and $2.5 million, respectively, in revenues that were included in the beginning deferred revenues balance for those periods.

During the three months ended March 31, 2022, and 2021, we recognized $31.7 million and $27.8 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, Takeda, Daiichi Sankyo and Genentech.

As of March 31, 2022, $87.4 million of the combined transaction prices for our Ipsen and Takeda collaborations were allocated to our research and development services performance obligations that had not yet been satisfied. See “Note 3. Collaboration Agreements and Business Development Activities” of the “Notes to Consolidated Financial Statements” included in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 for information about the expected timing to satisfy these performance obligations.

NOTE 3. COLLABORATION AGREEMENTS AND BUSINESS DEVELOPMENT ACTIVITIES

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 collaboration 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. Historically, we also entered into other collaborations with leading pharmaceutical companies pursuant to which we out-licensed other compounds and programs in our portfolio.

See “Note 3. Collaboration Agreements and Business Development Activities” to our Consolidated Financial Statements included in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, or as further described below, for additional information on certain 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,	
	2022	2021
License revenues	$ 24,614	$ 22,451
Collaboration services revenues	9,913	11,355
Total	$ 34,527	$ 33,806

As of March 31, 2022, $46.7 million of the transaction price was allocated to our research and development services performance obligations that have not yet been satisfied.

Takeda Collaboration

In January 2017, we entered into a collaboration and license agreement with Takeda for the commercialization and further development of cabozantinib. 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,	
	2022	2021
License revenues	$ 2,365	$ 1,301
Collaboration services revenues	3,702	4,135
Total	$ 6,067	$ 5,436

As of March 31, 2022, $40.6 million of the transaction price was allocated to our research and development services performance obligations that have not yet been satisfied.

Royalty Pharma

In October 2002, we established a product development and commercialization collaboration agreement with GlaxoSmithKline (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. Effective January 1, 2021, Royalty Pharma plc (Royal 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 U.S. market through September 2026, after which time U.S. royalties will revert back to GSK. Royalties earned by Royalty Pharma in connection with our sales of cabozantinib are included in cost of goods sold and in connection with sales by our collaboration partners are included as a reduction of collaboration services revenues. Such royalties were $13.1 million and $10.1 million during the three months ended March 31, 2022, and 2021, 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 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,	
	2022	2021
Profits on U.S. commercialization	$ 2,139	$ 1,794
Royalty revenues on ex-U.S. sales	$ 1,628	$ 951

Research Collaborations, In-Licensing Arrangements and Other Business Development Activities

Our research collaborations, in-licensing arrangements and other strategic transactions include upfront payments, development, regulatory, commercial milestone payments and royalty payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Certain of our research collaborations provide us exclusive options that give us the right to license programs developed under the research collaborations for further discovery and development. When we decide to exercise the options, we are required to pay an exercise fee and then assume the responsibilities for all subsequent clinical development, manufacturing and commercialization. In conjunction with each of these collaborative in-licensing arrangements, we were subject to upfront payments and will make payments for potential future development milestones of up to $254.3 million, regulatory milestones of up to $426.5 million and commercial milestones of up to $1,911.5 million, each in the aggregate per product or target, as well as royalties on future net product sales.

In conjunction with an asset purchase agreement entered into in 2021, we will make a $4.0 million payment upon the completion of the technology transfer of certain materials and documents specified in the asset purchase agreement. We will also make payments for potential future development milestones of up to $42.0 million and regulatory milestones of up to $22.5 million, per product.

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, 2022	December 31, 2021
Cash and cash equivalents	$ 723,269	$ 647,169
Restricted cash equivalents included in other long-term assets	14,007	16,722
Cash, cash equivalents, and restricted cash equivalents as reported in the accompanying Condensed Consolidated Statements of Cash Flows	$ 737,276	$ 663,891

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, 2022, restricted cash equivalents included $12.5 million of short-term investments, which is collateral under our January 2021 standby letter of credit to guarantee our obligation to fund a portion of the total tenant improvements related to our build-to-suit lease at our corporate campus. As we fund these tenant improvements, our restricted cash becomes available for operations. Our January 2021 standby letter of credit will remain effective through June 30, 2022.

Cash, Cash Equivalents, Restricted Cash Equivalents and Investments

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

	March 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 954,283	$ 5	$ (26)	$ 954,262
Corporate bonds	529,129	95	(7,123)	522,101
U.S. Treasury and government-sponsored enterprises	197,605	—	(1,141)	196,464
Municipal bonds	13,455	—	(169)	13,286
Total debt securities available-for-sale	1,694,472	100	(8,459)	1,686,113
Cash	97,602	—	—	97,602
Money market funds	87,255	—	—	87,255
Certificates of deposit	117,901	—	—	117,901
Total cash, cash equivalents, restricted cash equivalents and investments	$ 1,997,230	$ 100	$ (8,459)	$ 1,988,871

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Debt securities available-for-sale:				
Commercial paper	$ 945,801	$ 42	$ (2)	$ 945,841
Corporate bonds	541,774	876	(1,672)	540,978
U.S. Treasury and government-sponsored enterprises	33,965	1	(21)	33,945
Municipal bonds	12,924	15	(35)	12,904
Total debt securities available-for-sale	1,534,464	934	(1,730)	1,533,668
Cash	135,653	—	—	135,653
Money market funds	66,531	—	—	66,531
Certificates of deposit	119,056	—	—	119,056
Total cash, cash equivalents, restricted cash equivalents and investments	$ 1,855,704	$ 934	$ (1,730)	$ 1,854,908

Interest receivable was $2.6 million and $2.9 million as of March 31, 2022 and December 31, 2021, 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, 2022, and 2021.

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, 2022	
	Fair Value	Gross Unrealized Losses
Corporate bonds	$ 456,676	$ (7,123)
U.S. Treasury and government-sponsored enterprises	196,464	(1,141)
Commercial paper	32,460	(26)
Municipal bonds	13,286	(169)
Total	$ 698,886	$ (8,459)

	December 31, 2021	
	Fair Value	Gross Unrealized Losses
Corporate bonds	$ 385,053	$ (1,672)
Commercial paper	43,290	(2)
U.S. Treasury and government-sponsored enterprises	18,962	(21)
Municipal bonds	7,475	(35)
Total	$ 454,780	$ (1,730)

There were 197 and 133 investments in an unrealized loss position as of March 31, 2022 and December 31, 2021, respectively. All securities presented above have been in an unrealized loss position for less than twelve months except for two corporate bond securities with an aggregate fair value of $6.3 million and an aggregate immaterial unrealized loss as of March 31, 2022. During the three months ended March 31, 2022, and 2021, 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, 2022	December 31, 2021
Maturing in one year or less	$ 1,290,576	$ 1,168,256
Maturing after one year through five years	395,537	365,412
Total debt securities available-for-sale	$ 1,686,113	$ 1,533,668

NOTE 5. 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; and
- 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, 2022		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 954,262	$ 954,262
Corporate bonds	—	522,101	522,101
U.S. Treasury and government-sponsored enterprises	—	196,464	196,464
Municipal bonds	—	13,286	13,286
Total debt securities available-for-sale	—	1,686,113	1,686,113
Money market funds	87,255	—	87,255
Certificates of deposit	—	117,901	117,901
Total financial assets carried at fair value	$ 87,255	$ 1,804,014	$ 1,891,269

	December 31, 2021		
	Level 1	Level 2	Total
Commercial paper	$ —	$ 945,841	$ 945,841
Corporate bonds	—	540,978	540,978
U.S. Treasury and government-sponsored enterprises	—	33,945	33,945
Municipal bonds	—	12,904	12,904
Total debt securities available-for-sale	—	1,533,668	1,533,668
Money market funds	66,531	—	66,531
Certificates of deposit	—	119,056	119,056
Total financial assets carried at fair value	$ 66,531	$ 1,652,724	$ 1,719,255

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.

Forward Foreign Currency Contracts

We have 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, 2022, we had one forward contract outstanding to sell €7.5 million. The forward contract with 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 forward contract is considered a Level 2 in the fair value hierarchy of our fair value measurements. For the three months ended March 31, 2022, and 2021, we recognized $0.2 million and $0.4 million, respectively, of net 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. INVENTORY

Inventory consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Raw materials	$ 10,858	$ 8,867
Work in process	27,778	27,717
Finished goods	14,653	12,927
Total	$ 53,289	$ 49,511
Balance Sheet classification:		
Current portion included in inventory	$ 28,467	$ 27,493
Long-term portion included in other long-term assets	24,822	22,018
Total	$ 53,289	$ 49,511

NOTE 7. 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,	
	2022	2021
Research and development	$ 8,899	$ 12,396
Selling, general and administrative	10,860	22,257
Total stock-based compensation expense	$ 19,759	$ 34,653

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,	
	2022	2021
Stock options	$ 3,678	$ 4,694
Restricted stock units	13,073	11,669
Performance stock units	1,709	17,947
ESPP	1,299	343
Total stock-based compensation expense	$ 19,759	$ 34,653

As of March 31, 2022, 4,152,901 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, 2022, we granted 233,476 stock options with a weighted average exercise price of $19.02 per share and a weighted average grant date fair value of $7.51 per share. As of March 31, 2022, there were 12,635,435 stock options outstanding and $24.8 million of related unrecognized compensation expense.

In March 2022, we awarded to certain employees an aggregate of 1,003,482 (the target amount) RSUs that are subject to a total shareholder return (TSR) market condition (the TSR-based RSUs). 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 1, 2022 through January 3, 2025. Depending on the results relative to the TSR market condition, the holders of the TSR-based RSUs may earn up to 175% of the target amount of shares. 50% of the shares earned pursuant to the TSR-based RSU awards will vest at the end of the performance period, and the remainder will vest approximately one year later, subject to employee's continuous service. These TSR-based RSUs will be forfeited if the market condition at or above a threshold level is not achieved at the end of the performance period on January 3, 2025.

We used a Monte Carlo simulation model and the following assumptions to determine the grant date fair value of $33.17 per share for the TSR-based RSUs:

Fair value of the Company's common stock on grant date	$ 20.70
Expected volatility	46.85 %
Risk-free interest rate	1.59 %
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.

During the three months ended March 31, 2022, we granted 3,549,973 service-based RSUs with a weighted average grant date fair value of $20.51 per share. As of March 31, 2022, there were 11,635,329 RSUs outstanding, including the TSR-based RSUs, and $209.6 million of related unrecognized compensation expense.

Stock options and service-based RSUs granted to employees during the three months ended March 31, 2022 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 Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

As of March 31, 2022, there were 5,698,281 performance-based restricted stock units (PSUs) outstanding and $116.0 million of related unrecognized stock-based compensation expense. Expense recognition for PSUs commences when it is determined that achievement of the performance target is probable. For more information about our PSUs, see "Note 8. Employee Benefit Plans" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

NOTE 8. PROVISION FOR (BENEFIT FROM) INCOME TAXES

The effective tax rate for the three months ended March 31, 2022 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 during the period and the generation of federal tax credits, partially offset by state taxes. The effective 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.

NOTE 9. 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,	
	2022	2021
Numerator:		
Net income	$ 68,573	$ 1,601
Denominator:		
Weighted-average common shares outstanding — basic	319,582	312,473
Dilutive securities	3,707	8,814
Weighted-average common shares outstanding — diluted	323,289	321,287
Net income per share — basic	$ 0.21	$ 0.01
Net income per share — diluted	$ 0.21	$ 0.00

Dilutive securities included outstanding stock options, unvested RSUs, including TSR-based RSUs, 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,	
	2022	2021
Anti-dilutive securities and contingently issuable shares excluded	16,522	10,007

NOTE 10. COMMITMENTS AND CONTINGENCIES

Overview

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. Patents No. 8,877,776 (salt and polymorphic forms), 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, for CABOMETYX. MSN's initial notice letter did not provide a Paragraph IV certification against U.S. Patents No. 7,579,473 (composition of matter) or 8,497,284 (methods of treatment), each of which is listed in the Orange Book. On October 29, 2019, we filed a complaint in the United States District Court for the District of Delaware (the Delaware District Court) for patent infringement against MSN asserting infringement of 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 the asserted claims of U.S. Patent No. 8,877,776 are invalid and not infringed. On May 5, 2020, we received notice from MSN that it had amended its ANDA to include additional Paragraph IV certifications. In particular, the ANDA requested approval to market a generic version of CABOMETYX tablets prior to expiration of two previously unasserted CABOMETYX patents: U.S. Patents No. 7,579,473 and 8,497,284. On May 11, 2020, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patents No. 7,579,473 and 8,497,284 arising from MSN's amended ANDA filing with the FDA. Neither of our complaints have alleged infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757. On May 22, 2020, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 7,579,473 and 8,497,284 are 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 (salt and polymorphic forms) is invalid and would not be infringed by MSN if its generic version of CABOMETYX tablets were approved by the FDA. U.S. Patent No. 9,809,549 is not listed in the Orange Book. 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.

On October 1, 2021, pursuant to a stipulation between us and MSN, the Delaware District Court entered an order that (i) MSN's submission of its ANDA constitutes infringement of certain claims relating to U.S. Patents No. 7,579,473 and 8,497,284, if those claims are not found to be invalid, and (ii) upon approval, MSN's commercial manufacture, use, sale or offer for sale within the U.S., and importation into the U.S., of MSN's ANDA product prior to the expiration of U.S. Patents No. 7,579,473 and 8,497,284 would also infringe certain claims of each patent, if those claims are not found to be invalid. Then, on October 12, 2021, pursuant to a separate stipulation between us and MSN, the Delaware District Court entered an order dismissing MSN's counterclaims with respect to U.S. Patent No. 9,809,549. In our complaints, we are seeking, among other relief, an order that the effective date of any FDA approval of MSN's ANDA be a date no earlier than the expiration of all of U.S. Patents No. 7,579,473, 8,497,284 and 8,877,776, the latest of which expires on October 8, 2030, and equitable relief enjoining MSN from infringing these patents. In an effort to streamline the case, the parties have narrowed their assertions. On April 8, 2022, MSN withdrew its validity challenge to U.S. Patent No. 8,877,776. On April 14, 2022, we agreed not to assert U.S. Patent No. 8,497,284 at trial and MSN has, correspondingly, agreed to withdraw its validity challenges to U.S. Patent No. 8,497,284, as well as claims 1-4 and 6-7 of U.S. Patent No. 7,579,473. As a result of this narrowing, the upcoming trial will address two issues: (1) infringement of claims 1 and 2 of the U.S. Patent No. 8,877,776; and (2) validity of claim 5 of the U.S. Patent No. 7,579,473. A three-day bench trial has been scheduled to begin on May 16, 2022.

On January 11, 2022, we received notice from MSN that it had further 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 three previously-unasserted CABOMETYX patents that are now listed in the Orange Book: U.S. Patents No. 11,091,439 (salt and polymorphic forms), 11,091,440 (formulations) and 11,098,015 (methods of treatment). On February 23, 2022, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 (the 2022 MSN ANDA Complaint) arising from MSN's further amendment of its ANDA filing with the FDA. In the 2022 MSN ANDA Complaint, we are seeking, among other remedies, equitable relief enjoining MSN from infringing these patents, as well as an order that the effective date of any FDA approval of MSN's ANDA would be a date no earlier than the expiration of the patents identified in the 2022 MSN ANDA Complaint, the latest of which expires on January 15, 2030. The 2022 MSN ANDA Complaint is a new case against MSN involving Exelixis patents that are different from those asserted in the consolidated Civil Action Nos. 19-02017 and 20-00633 described above. On February 25, 2022, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 are invalid and not infringed. A bench trial in connection with the 2022 MSN ANDA Complaint has been scheduled for May 2023.

In May 2021, we received notice letters from Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as Teva) regarding an ANDA Teva submitted to the FDA, requesting approval to market a generic version of CABOMETYX tablets. Teva's notice letters included a Paragraph IV certification with respect to our U.S. Patents No. 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 letters did not provide a Paragraph IV certification against any additional CABOMETYX patents. On June 17, 2021, we filed a complaint in the Delaware District Court for patent infringement against Teva, along with Teva Pharmaceutical Industries Limited (Teva Parent), asserting infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757 arising from Teva's ANDA filing with the FDA. On August 27, 2021, Teva filed its answer and counterclaims to the complaint, alleging that the asserted claims of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757 are invalid and not infringed, and on August 23, 2021, we and Teva entered into a stipulation wherein Teva Parent was dismissed without prejudice from this lawsuit and agreed to be bound by any stipulation, judgment, order or decision rendered as to Teva, including any appeals and any order granting preliminary or permanent injunctive relief against Teva. On September 17, 2021, we filed an answer to Teva's counterclaims. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva's ANDA be a date no earlier than the expiration of all of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757, the latest of which expires on July 9, 2033, and equitable relief enjoining Teva from infringing these patents. On February 8, 2022, the parties filed a stipulation to stay all proceedings, which was granted by the Delaware District Court on February 9, 2022. On February 11, 2022, this case was administratively closed.

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.

NOTE 11. SUBSEQUENT EVENTS

Build-to-Suit Lease

In April 2022, the office building (New Premises) associated with our October 2019 build-to-suit lease agreement (Build-to-Suit Lease) was substantially completed. The New Premises is approximately 220,000 square feet and is in Alameda, California, adjacent to our existing corporate headquarters. The Build-to-Suit Lease term is 242 months, includes two five-year options to extend the term of the lease and a one-time option to terminate the lease after 180 months. In addition to the lease payments, we are also responsible for paying operating expenses related to the New Premises. For more information about our Build-to-Suit Lease, see "Note 11. Commitments and Contingencies" of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

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, 2021, *filed with the Securities and Exchange Commission (SEC) on February 18, 2022.*

Overview

We are an oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for patients with difficult-to-treat cancers. Using our considerable drug discovery, development and commercialization resources and capabilities, we have invented and brought to market innovative therapies that appropriately balance patient benefits and risks; we will continue to build on this foundation as we strive to provide cancer patients with new treatment options that improve upon current standards of care.

Today, four products that originated in Exelixis laboratories are available to be prescribed to patients. Sales related to our flagship molecule, cabozantinib, account for the large majority of our revenues. Cabozantinib is an inhibitor of multiple tyrosine kinases including MET, AXL, VEGF receptors and RET and has been approved by the U.S. Food and Drug Administration (FDA) and in 61 other countries as: CABOMETYX® (cabozantinib) tablets approved for advanced renal cell carcinoma (RCC), both alone and in combination with Bristol-Myers Squibb Company's (BMS) OPDIVO® (nivolumab), for previously treated hepatocellular carcinoma (HCC) and, currently by the FDA and European Commission (EC), for previously treated, radioactive iodine (RAI)-refractory differentiated thyroid cancer (DTC); and COMETRIQ® (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer (MTC). For physicians treating these types of cancer, cabozantinib has become or is becoming an important medicine in their selection of effective therapies.

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).

Our plan is to utilize our operating cash flows and cash and investments to expand the cabozantinib franchise by potentially adding new indications in areas of unmet medical need. We will also leverage our operating cash flows to continue advancing our diverse small molecule and biotherapeutics programs, exploring multiple modalities and mechanisms of action to discover new oncology drugs. So far, these drug discovery and preclinical activities have resulted in four clinical-stage compounds: XL092, a next-generation oral tyrosine kinase inhibitor (TKI); XB002, an antibody drug conjugate (ADC) that targets tissue factor (TF); XL102, a potent, selective and orally bioavailable covalent inhibitor of cyclin-dependent kinase 7 (CDK7); and XL114, a novel anti-cancer compound that inhibits the CARD11-BCL10-MALT1 (CBM) complex.

Cabozantinib Franchise

The FDA first approved CABOMETYX as a monotherapy for previously treated patients with advanced RCC in April 2016, and then for previously untreated patients with advanced RCC in December 2017. In January 2021, the CABOMETYX label was expanded to include first-line advanced RCC in combination with OPDIVO, which was the first CABOMETYX regimen approved for treatment in combination with an immune checkpoint inhibitor (ICI). In addition to RCC, in January 2019, the FDA approved CABOMETYX for the treatment of patients with HCC previously treated with sorafenib, and then in September 2021, the FDA approved CABOMETYX for the treatment of adult and pediatric patients 12 years of age and older

with locally advanced or metastatic DTC that has progressed following prior VEGF receptor-targeted therapy and who are RAI-refractory or ineligible.

To develop and commercialize CABOMETYX and COMETRIQ outside the U.S., we have entered into license agreements with Ipsen and Takeda. We granted to Ipsen the rights to develop and commercialize cabozantinib outside of the U.S. and Japan, and to Takeda we granted 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 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), the United Kingdom (U.K.) 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 EC for CABOMETYX in combination with OPDIVO as a first-line treatment for patients with advanced RCC, followed by additional regulatory approvals for the combination in other territories beyond the EU. Most recently, in May 2022, we announced that Ipsen received regulatory approval from the EC for CABOMETYX as a monotherapy for the treatment of adult patients with locally advanced or metastatic, RAI-refractory or ineligible DTC and who have progressed during or after prior systemic therapy. With respect to the Japanese market, Takeda received Manufacturing and Marketing Approvals in 2020 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 August 2021, Takeda and Ono Pharmaceutical Co., Ltd. (Ono), BMS' development and commercialization partner in Japan, received Manufacturing and Marketing Approval from the Japanese MHLW of CABOMETYX in combination with OPDIVO as a treatment for unresectable 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 potentially benefit from this medicine. We continue to evaluate cabozantinib, both as a single agent and in combination with ICIs, in a broad development program comprising over 100 ongoing or planned clinical trials across multiple tumor types. 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 (IST) program. The data from these third-party clinical trials have helped advance our development program for the cabozantinib franchise by informing subsequent label-enabling trials, including COSMIC-311, our phase 3 pivotal trial evaluating cabozantinib in previously treated patients with RAI-refractory DTC, from which positive results served as the basis for the FDA's and EC's approvals of CABOMETYX for DTC.

Building on preclinical and clinical observations that cabozantinib in combination with ICIs may promote a more immune-permissive tumor environment, we initiated numerous pivotal studies to further explore these combination regimens. The first of these studies to deliver results was CheckMate -9ER, a phase 3 pivotal trial evaluating the combination of CABOMETYX and OPDIVO compared to sunitinib in previously untreated, advanced or metastatic RCC, and positive results from CheckMate -9ER served as the basis for the FDA's, EC's and MHLW's approvals of CABOMETYX in combination with OPDIVO as a first-line treatment of patients with advanced RCC in January 2021, March 2021 and August 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 July 2022.

To expand our exploration of combinations with ICIs, we also initiated multiple trials evaluating cabozantinib in combination with F. Hoffmann-La Roche Ltd.'s (Roche) ICI, atezolizumab, beginning in 2017 with COSMIC-021, a broad phase 1b study evaluating the safety and tolerability of cabozantinib in combination with atezolizumab in patients with a wide variety of locally advanced or metastatic solid tumors. The 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, a phase 3 pivotal trial evaluating cabozantinib in combination with atezolizumab versus sorafenib in previously untreated advanced HCC, 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 non-small cell lung cancer (NSCLC), metastatic castration-resistant prostate cancer (mCRPC) and advanced RCC, respectively. CONTACT-01 and CONTACT-03 are sponsored by Roche and co-funded by us, and we announced the completion of enrollment for the two trials in November 2021 and January 2022, respectively, with interim results from both trials expected in the second half of 2022; CONTACT-02 is sponsored by us and co-funded by Roche, with enrollment ongoing globally. In June 2021, we

announced that the COSMIC-312 phase 3 trial met one of the primary endpoints, demonstrating significant improvement in blinded independent radiology committee (BIRC) assessed PFS at the planned primary analysis, reducing the risk of disease progression or death by 37% compared with sorafenib. However, the final analysis for the second primary endpoint of overall survival (OS), which we announced in March 2022, showed neither improvement nor detriment in OS for cabozantinib in combination with atezolizumab versus sorafenib. Based on this outcome for OS and the rapidly evolving treatment landscape for previously untreated HCC, we do not intend to submit a supplemental New Drug Application (sNDA) to the FDA for the combination regimen.

Pipeline Activities

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 enter the clinic following our re-initiation of drug discovery activities in 2017 was XL092, a next-generation oral TKI 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 a similar target profile while improving key characteristics, including the pharmacokinetic half-life. To date, we have initiated two large phase 1b clinical trials studying XL092: STELLAR-001 and STELLAR-002. STELLAR-001 is a phase 1b clinical trial evaluating XL092, both as a monotherapy and in combination with either atezolizumab or avelumab, an ICI developed by Merck KGaA Damstadt, Germany and Pfizer Inc. We have established recommended doses for single-agent XL092 and XL092 in combination with atezolizumab and have begun enrolling expansion cohorts for patients with clear cell RCC, hormone-receptor positive breast cancer and mCRPC, and we are continuing to enroll patients into dose-escalation cohorts for XL092 in combination with avelumab; additional expansion cohorts for STELLAR-001 may include non-clear cell RCC, colorectal cancer (CRC) and urothelial carcinoma (UC). STELLAR-002 is a phase 1b clinical trial evaluating XL092 in combination with either nivolumab or with nivolumab and ipilimumab. An amendment is also underway to remove the previously included triplet combination of XL092, nivolumab and Nektar Therapeutics' bempegaldesleukin; we are also negotiating with a partner to replace that combination regimen with a different XL092 triplet combination regimen. We are enrolling patients with advanced solid tumors in dose-escalation cohorts, and depending on the dose-escalation results, STELLAR-002 may enroll expansion cohorts for patients with clear cell and non-clear cell RCC, mCRPC and UC. To better understand the individual contribution of the therapies, treatment arms in the expansion cohorts may include XL092 as a single-agent in addition to the ICI combination regimens. We plan to initiate the first global phase 3 pivotal trial for the compound in the second quarter of 2022, and other phase 3 pivotal trials may follow throughout the year. This first planned global phase 3 pivotal trial, STELLAR-303, will evaluate XL092 in combination with atezolizumab versus regorafenib in patients with metastatic non-microsatellite instability-high CRC who have progressed after or are intolerant to the current standard of care.

We also augment our small molecule discovery activities through research collaborations and in-licensing arrangements with other companies. The most advanced compounds to emerge from these arrangements are XL102 , the lead program targeting CDK7 under our collaboration with Aurigene Discovery Technologies Limited (Aurigene), and XL114, Aurigene's novel anti-cancer compound that inhibits the CBM complex. Based on encouraging preclinical data, we exercised our exclusive options to license XL102 and XL114 from Aurigene and initiated phase 1 clinical trials evaluating XL102 and XL114 in January 2021 and April 2022, respectively, and we expect to provide clinical updates from the phase study of XL102 in the second half of 2022.

Beyond small molecules, we have also launched rigorous efforts to discover and advance various biotherapeutics that have the potential to become anti-cancer therapies, such as bispecific antibodies, ADCs and other innovative treatments. ADCs in particular present a unique opportunity for new cancer treatments, given their capabilities to deliver anti-cancer payload drugs to targets with increased precision while minimizing impact on healthy tissues, and this biotherapeutic approach has been validated by multiple regulatory approvals for the commercial sale of ADCs in the past several years. To facilitate the growth of these programs, we have established multiple research collaborations and in-licensing arrangements and entered into other strategic transactions that provide us with 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 multispecific antibodies. We have already made significant progress under these arrangements and believe we will continue to do so in the remainder of 2022 and in future years:

- *Iconic.* We in-licensed XB002, our lead TF-targeting ADC program, from Iconic, Inc. (Iconic) in December 2020 and then initiated a phase 1 clinical trial in June 2021. We expect to provide clinical updates from the trial in the second half of 2022. In December 2021, we amended our exclusive option and license agreement with Iconic to acquire broad rights to use the anti-TF antibody used in XB002 for any application, including conjugated to other payloads, as well as rights within oncology to a number of other anti-TF antibodies developed by Iconic, including for use in ADCs and multispecific biotherapeutics.
- *WuXi Bio.* We expanded our access to antibodies through arrangements with WuXi Biologics Ireland Limited, a wholly owned subsidiary of WuXi Biologics (Cayman) Inc. (individually and collectively referred to as WuXi Bio). We are focused on leveraging WuXi Bio's panel of monoclonal antibodies (mAbs) against an undisclosed target for the development of ADC, bispecific and certain other novel tumor-targeting biotherapeutics.
- *GamaMabs.* We completed an asset purchase from GamaMabs Pharma SA (GamaMabs) in May 2022. In the transaction, we acquired 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.
- *Invenra*. We expanded our collaboration with Invenra, Inc. (Invenra) several times since our first engagement in 2018, most recently in August 2021 to include an additional 20 oncology targets.
- *NBE and Catalent*. We entered into collaborations with NBE-Therapeutics AG (NBE) and Catalent, Inc.'s wholly owned subsidiaries Redwood Bioscience, Inc., R.P. Scherer Technologies, LLC and Catalent Pharma Solutions, Inc. (individually and collectively referred to as Catalent) in September 2020. These platform collaborations allow us to utilize their site-specific conjugation technologies and payloads to construct ADCs using the antibodies we have sourced from our arrangements with WuXi Bio, GamaMabs and Invenra.
- *Adagene*. We entered into a collaboration with Adagene Inc. (Adagene) in February 2021, focused on using Adagene's SAFEbody® technology to develop novel masked ADCs or other innovative biotherapeutics, with the potential to develop ADCs or other biotherapeutics with improved therapeutic index.

As a direct result of these arrangements, we designated XB010, our first ADC advanced internally, as a development candidate in late 2021. XB010, which targets the tumor antigen 5T4, incorporates antibodies sourced from Invenra and was constructed using Catalent's SMARTag® site-specific bioconjugation platform.

As of the date of this Quarterly Report, we are currently advancing more than 10 discovery programs and expect to progress up to five new development candidates into preclinical development during 2022. In addition, we will continue to engage in business development initiatives with the goal of acquiring and in-licensing promising oncology platforms and assets and then further characterize and develop them utilizing our established preclinical and clinical development infrastructure.

COVID-19 Update

As of the date of this Quarterly Report on Form 10-Q, the COVID-19 pandemic continues to have a modest impact on our business operations. While the pandemic has created operational difficulties and complexities, we have thus far been successful at devising solutions to mitigate its impact. We will continue to monitor new developments that could pose additional risks for us, including the spread of the Omicron and other SARS-CoV-2 variants in the U.S. and other countries and the potential emergence of new variants that may prove especially contagious or virulent. 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 2022, and potentially into 2023.

First Quarter 2022 Business Updates and Financial Highlights

During the first quarter of 2022**,** 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 2022, we appointed Vicki L. Goodman, M.D., as Executive Vice President, Product Development & Medical Affairs, and Chief Medical Officer. Dr. Goodman had previously served as Vice President, Clinical Research and Therapeutic Area Head, Late Stage Oncology at Merck & Co.

- In January 2022, we announced the completion of enrollment for CONTACT-03, a phase 3 pivotal trial evaluating the efficacy and safety of cabozantinib in combination with atezolizumab versus cabozantinib alone in patients with locally advanced or metastatic RCC who progressed during or following treatment with an ICI as the immediate preceding therapy. Based on current event rates, we anticipate announcing results of PFS and the first interim OS analysis in the second half of 2022.
- In January 2022, we announced an amendment to our exclusive option and license agreement with Iconic to acquire broad rights to use the anti-TF antibody incorporated into XB002 for any application, including conjugated to other payloads, as well as rights within oncology to a number of other anti-TF antibodies developed by Iconic, including for use in ADCs and multispecific biotherapeutics.
- In January 2022, we presented encouraging data from two early-stage studies evaluating cabozantinib in combination with ICIs in patients with previously treated CRC at the 2022 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium: cohort 16 from COSMIC-021, evaluating cabozantinib in combination with atezolizumab in patients with metastatic CRC who were previously treated with fluoropyrimidine-containing chemotherapy; and cohort 2 from CAMILLA, the phase 2 IST evaluating cabozantinib in combination with durvalumab in patients with advanced mismatch repair proficient/micro satellite stable CRC patients who were chemotherapy-refractory.
- In February 2022, cabozantinib was the subject of multiple data presentations in forms of RCC and other genitourinary cancers at the 2022 ASCO Genitourinary Cancers Symposium.
- In February 2022 , we filed a patent lawsuit in the United States District Court for the District of Delaware (the Delaware District Court) against MSN Pharmaceuticals, Inc. (MSN) asserting infringement of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 arising from MSN's further amendment of its Abbreviated New Drug Application (ANDA), originally filed with the FDA in September 2019 for a generic version of CABOMETYX tablets and first amended by MSN in May 2020. We are seeking, among other relief, an order that the effective date of any FDA approval of MSN's ANDA would be a date no earlier than the expiration of all of the patents referenced in our lawsuit, the latest of which expires on January 15, 2030. This is a new case against MSN involving Exelixis patents that are different from those asserted previously in consolidated patent lawsuits that we filed in 2019 and 2020. For a more detailed discussion of this litigation matter, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q.
- In March 2022, we announced results from the final OS analysis of COSMIC-312 trial, which showed neither improvement nor detriment in OS for cabozantinib in combination with atezolizumab versus sorafenib in patients with previously untreated advanced HCC. Based on this outcome for OS and the rapidly evolving treatment landscape for previously untreated HCC, we do not intend to submit an sNDA to the FDA for the combination regimen.In April 2022, we announced the initiation of a phase 1 clinical trial evaluating XL114 as a monotherapy in patients with non-Hodgkin's Lymphoma (NHL).
- In May 2022, we announced that Ipsen received regulatory approvals from the EC and Health Canada for CABOMETYX as a monotherapy for patients with previously treated, RAI-refractory DTC.
- In June 2022, cabozantinib will be the subject of multiple data presentations in NSCLC, UC, RCC, head and neck squamous cell carcinoma, and DTC at the 2022 ASCO Annual Meeting.

Financial Highlights

- Net product revenues for the first quarter of 2022 were $310.3 million, compared to $227.2 million for the first quarter of 2021.
- Total revenues for the first quarter of 2022 were $356.0 million, compared to $270.2 million for the first quarter of 2021.
- Research and development expenses for the first quarter of 2022, were $156.7 million, compared to $159.3 million for the first quarter of 2021.
- Selling, general and administrative expenses for the first quarter of 2022 were $102.9 million, compared to $102.4 million for the first quarter of 2021.
- Provision for (benefit from) income taxes for the first quarter of 2022 was $16.7 million, compared to $(3.6) million for the first quarter of 2021.
- Net income for the first quarter of 2022 was $68.6 million, or $0.21 per share, basic and diluted, compared to net income of $1.6 million, or $0.01 per share, basic and $0.00 per share, diluted, for the first quarter of 2021.

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

Outlook, Challenges and Risks

We will continue to face a number of challenges and risks that may impact our ability to execute on our 2022 business objectives. 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 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 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 conducting 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 expanding access to, and restricting the prices of, pharmaceuticals.

Achievement of our 2022 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 competitive landscape, including through evaluation of therapies that combine ICIs with other targeted agents, 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 in approved indications. Moreover, the complexities of this 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 and Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (individually and collectively referred to as 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. 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 biopharmaceutical industry with development and commercial operations. For a more detailed discussion of challenges and risks we face, see "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Fiscal Year Convention

We have adopted a 52- or 53-week fiscal year policy that generally ends on the Friday closest to December 31st. Fiscal year 2022, which is a 52-week fiscal year, will end on December 30, 2022 and fiscal year 2021, which was a 52-week fiscal year, ended on December 31, 2021. For convenience, references in this report as of and for the three months ended April 1, 2022 and April 2, 2021, and as of and for the fiscal year ending December 30, 2022 are indicated as being as of and for the three months ended March 31, 2022 and March 31, 2021, and the year ending December 31, 2022, respectively.

Results of Operations

Revenues

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

	Three Months Ended March 31,		Percent Change
	2022	2021	
Net product revenues	$ 310,298	$ 227,212	37 %
License revenues	32,067	27,528	16 %
Collaboration services revenues	13,615	15,490	-12 %
Total revenues	$ 355,980	$ 270,230	32 %

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
	2022	2021	
Gross product revenues	$ 448,237	$ 314,205	43 %
Discounts and allowances	(137,939)	(86,993)	59 %
Net product revenues	$ 310,298	$ 227,212	37 %

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

	Three Months Ended March 31,		Percent Change
	2022	2021	
CABOMETYX	$ 302,812	$ 223,595	35 %
COMETRIQ	7,486	3,617	107 %
Net product revenues	$ 310,298	$ 227,212	37 %

The increase in net product revenues for the three months ended March 31, 2022, as compared to the corresponding prior year period, was primarily related to a 33% increase 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 in January 2021, in part due to the longer duration of therapy for this combination and, to a lesser extent, a 2% increase in the average net selling price of CABOMETYX.

We project our net product revenues for the remainder of 2022 may increase, as compared to the corresponding prior year period, for similar reasons noted above.

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 Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

The increase in discounts and allowances for the three months ended March 31, 2022,as compared to the corresponding prior year period, was primarily from higher utilization by covered entities in the 340B Drug Pricing Program, an increase in Medicaid utilization and an increase in co-pay assistance for commercially insured patients.

Discounts and allowances as a percentage of gross revenues have increased over time as the number of patients participating in government programs has increased and as the discounts given and rebates paid to government payers also increased. We project this trend will continue and that our discounts and allowances as a percentage of gross revenues may increase during the remainder of 2022, as compared to the corresponding prior year period.

License Revenues

License revenues generally include: (a) 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; (b) royalty revenues; and (c) the profit on the U.S. commercialization of COTELLIC from Genentech.

Royalty revenues increased primarily as a result of increases in Ipsen's net sales of cabozantinib outside of the U.S. and Japan. Ipsen royalties were $24.6 million for the three months ended March 31, 2022 compared to $22.5 million for the corresponding prior year period. 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 regulatory approval in new territories, including regulatory approval in the EU for the combination therapy of CABOMETYX and OPDIVO received in March 2021. Royalty revenues for the three months ended March 31, 2022 also included $2.4 million, compared to $1.3 million for the corresponding prior year period, related to Takeda's net sales of CABOMETYX which have continued to grow since their first commercial sale of product in Japan in 2020. Additionally, Takeda royalty revenues have increased due to the August 2021 regulatory approval in Japan for the combination therapy of CABOMETYX and OPDIVO. As of March 31, 2022, CABOMETYX is approved and is commercially available in 61 countries outside the U.S.

Our share of profits on the U.S. commercialization of COTELLIC under our collaboration agreement with Genentech was $2.1 million for the three months ended March 31, 2022, as compared to $1.8 million for the corresponding prior year period. We also earned royalties on ex-U.S. net sales of COTELLIC by Genentech of $1.6 million for the three months ended March 31, 2022, compared to $1.0 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.

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, and product supply revenues, which are net of product supply costs and the royalties we pay on sales by Ipsen and Takeda of products containing cabozantinib.

Development cost reimbursements were $17.3 million for the three months ended March 31, 2022, compared to $18.3 million for the corresponding prior year period. The decrease in development cost reimbursements for the three months ended March 31, 2022, as compared to the corresponding prior year period, is primarily attributable to a decrease in spending on the COSMIC-312 and COSMIC-021 studies, partially offset by an increase in spending on CONTACT-02 and development cost reimbursements related to Ipsen's decision to opt in and co-fund COSMIC-311 development costs in the second quarter of 2021.

Collaboration services revenues were reduced by $3.8 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, 2022, compared to $3.3 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 2022, as compared to the corresponding prior year period, primarily as a result of decreased development cost reimbursements related to Ipsen's opt in and co-funding of COSMIC-311 and the related cumulative catch-up in development cost reimbursements recognized in 2021 for which no similar event is projected to occur in 2022**.**

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
	2022	2021	
Cost of goods sold	$ 13,203	$ 13,198	0 %
Gross margin	96 %	94 %	

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, excess and obsolete inventory, and other third-party logistics costs. Cost of goods sold for the three months ended March 31, 2022, as compared to the corresponding prior year period was consistent. The increase in royalties as a result of increased U.S. CABOMETYX sales was offset by lower period costs. We project our gross margin will not change significantly during the remainder of 2022.

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 and biologics 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 Change
	2022	2021	
Research and development expenses:			
Development:			
Clinical trial costs	$ 59,998	$ 60,691	-1 %
Personnel expenses	34,266	28,884	19 %
Consulting and outside services	6,436	5,289	22 %
Other development costs	9,369	7,284	29 %
Total development	$ 110,069	$ 102,148	8 %
Drug discovery:			
License and other collaboration costs[1]	9,651	28,438	-66 %
Other drug discovery [2]	17,831	11,287	58 %
Total drug discovery	27,482	39,725	-31 %
Stock-based compensation	8,899	12,396	-28 %
Other research and development[3]	10,221	5,019	104 %
Total research and development expenses	$ 156,671	$ 159,288	

(1) Primarily includes upfront license fees, development milestone payments, program initiation fees, and research funding commitments associated with programs in preclinical development stage.
(2) Primarily includes personnel expenses, consulting and outside services and laboratory supplies.
(3) Includes the allocation of general corporate costs to research and development services, and development cost reimbursements in connection with our collaboration arrangement with Roche executed in December 2019.

The decrease in research and development expenses for the three months ended March 31, 2022, as compared to the corresponding prior year period, was primarily related to decreases in license and other collaboration costs, stock-based compensation and clinical trial costs, which were partially offset by increases in personnel expenses, other drug discovery and other research and development costs. License and other collaboration costs decreased as compared to the corresponding prior year period primarily due to decreases in upfront license fees and program initiation fees related to business development activities. Stock-based compensation expense decreased as compared to the corresponding prior year period due primarily to higher expense related to performance-based restricted stock units (PSUs) granted in 2019 that became probable of achievement in the first quarter of 2021. Clinical trial costs, which include services performed by third-party contract research organizations and other vendors who support our clinical trials, decreased as compared to the corresponding prior year period primarily due to lower costs associated with the COSMIC-312, COSMIC-313, and COSMIC-021 studies which were partially offset by increases in costs associated with XL092, CONTACT-02, XB002 and CONTACT-03 studies. Personnel expenses increased primarily due to an increase in headcount to support our expanding discovery and development organization.

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 a significant amount of our development efforts on cabozantinib to maximize the therapeutic and commercial potential of this compound and, as a result, we project that a substantial 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 ongoing company-sponsored studies resulting from this program include: COSMIC-313, for which BMS is providing nivolumab and ipilimumab free of charge and CONTACT-02 for which Roche is sharing the development costs and providing atezolizumab free of charge.

We are expanding our oncology product pipeline through 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 increase for the remainder of 2022, as compared to the corresponding prior year period, 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 current early-stage trials evaluating XL092, XB002, XL102 and XL114 and anticipated business development activities.

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
	2022	2021	
Selling, general and administrative expenses	$ 92,003	$ 80,094	15 %
Stock-based compensation	10,860	22,257	-51 %
Total selling, general and administrative expenses	$ 102,863	$ 102,351	1 %

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

Selling, general and administrative expenses for the three months ended March 31, 2022, as compared to the corresponding prior year period, remained relatively constant as increases in personnel expenses and marketing costs were

offset by a decrease in stock-based compensation expense. Personnel expenses increased as compared to the corresponding prior year period, primarily due to increases in administrative headcount to support our commercial and research and development organizations. Marketing costs increased as compared to the corresponding prior year period in support of the commercialization of the combination therapy of CABOMETYX and OPDIVO for the treatment of advanced RCC following approval by the FDA in January 2021. The decrease in stock-based compensation expense for the three months ended March 31, 2022, as compared to the corresponding prior year period was primarily due to higher compensation expense associated with the PSUs granted in 2019 that became probable of achievement in the first quarter of 2021.

We project our selling, general and administrative expenses may continue to increase for the remainder of 2022 as compared to the corresponding prior year period primarily driven by our continuing commercial investment in CABOMETYX and the growth of the broader organization.

Non-operating Income

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

	Three Months Ended March 31,		Percent Change
	2022	2021	
Interest income	$ 1,822	$ 2,682	-32 %
Other income (expense), net	164	(90)	n/a
Non-operating income	$ 1,986	$ 2,592	-23 %

The decrease in non-operating income for the three months ended March 31, 2022, as compared to the corresponding prior year period was primarily the result of a decrease in interest income due to lower interest rates.

Provision for (Benefit From) Income Taxes

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

	Three Months Ended March 31,		Percent Change
	2022	2021	
Provision for (benefit from) income taxes	$ 16,656	$ (3,616)	n/a

The effective tax rate for the three months ended March 31, 2022 differed from the U.S. federal statutory 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, partially offset by state taxes. We recorded a benefit from income taxes for the three months ended March 31, 2021 as a result of the reported pre-tax loss. 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.

Liquidity and Capital Resources

As of March 31, 2022, we had $2.0 billion in cash, cash equivalents, restricted cash equivalents and investments, compared to $1.9 billion as of December 31, 2021. 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.

Our primary cash requirements for operating activities, which we project will increase for the remainder of 2022, compared to the corresponding period in 2021, are for: employee related expenditures; costs related to our development programs including payments to third party contract research organizations that conduct and manage global clinical trials; drug discovery programs, including payments made to collaboration partners for in-licensing arrangements relative to upfront and option exercise fees, research and development funding, and development, regulatory and commercial milestones; income tax payments, royalty payments on our net product sales; and costs of inventory and our leased facilities. Our primary source of operating cash is cash collections from customers related to net product sales which we project will increase for the remainder of 2022 compared to the corresponding period in 2021 and cash collections from our commercial collaboration arrangements with Ipsen, Takeda and others related to royalties earned, the achievement of

certain development, regulatory and commercial milestones as well as cash payments to us for cost reimbursements under certain of our development programs. The timing of cash generated from commercial collaborations and cash payments required for in-licensing collaborations relative to upfront payments, initiation fees, milestone payments and cost reimbursements may vary from period to period.

We also have cash requirements related to capital expenditures to support the planned growth of our business including investments in laboratory facilities and equipment. We project that 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 strategic transactions that align with our oncology drug development, and 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 based on 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 $14.0 million and $16.7 million as of March 31, 2022 and December 31, 2021, respectively.

In January 2021, we entered into a standby letter of credit as guarantee of our obligation to fund our portion of the 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 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, 2022, restricted cash equivalents included $12.5 million of short-term investments as collateral under our standby letter of credit for our portion of the tenant improvements.

Sources and Uses of Cash

	March 31, 2022	December 31, 2021	Percent Change
Working capital	$ 1,553,664	$ 1,497,157	4 %
Cash, cash equivalents, restricted cash equivalents, and investments	$ 1,988,871	$ 1,854,908	7 %

Working capital: The increase in working capital as of March 31, 2022, as compared to December 31, 2021, was primarily due to the favorable impacts to our net current assets resulting from our net income during the first quarter of 2022 and the reclassification of certain investments from long-term to short term assets. In the future, our working capital may be impacted by one or both of these factors or other factors, the amounts and timing of which are variable.

Cash, cash equivalents, restricted cash equivalents and investments: Cash and cash equivalents primarily consist of cash deposits held at major banks, commercial paper and other securities with original maturities 90 days or less. Restricted cash equivalents and investments relate to our letter of credit agreements and are invested in short-term marketable securities. For additional information regarding our cash, cash equivalents, restricted cash equivalents and investments, see “Note 4. Cash and Investments,” in our “Notes to Condensed Consolidated Financial Statements” included in Part I, Item 1 of this Quarterly Report on Form 10-Q. The increase in cash, cash equivalents, restricted cash equivalent and investments at March 31, 2022 compared to December 31, 2021, was primarily due to cash inflows generated by our operations, including collections of amounts due from customers, collection of a $100.0 million milestone payment from Ipsen, partially offset by operating cash payments for employee related expenditures, our development and discovery programs, and capital expenditures.

Cash flow activities were as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net cash provided by operating activities	$ 147,719	$ 39,544
Net cash (used in) provided by investing activities	$ (74,539)	$ 62,255
Net cash provided by (used in) financing activities	$ 205	$ (2,650)

Our primary source of operating cash flows is cash collections from customers related to our net product sales and cash collections from our commercial collaboration arrangements. Our primary uses of cash from operating activities are for employee related costs, costs related to our development and discovery programs, income tax payments, cash payments for inventory, royalty payments on our net product sales, and our leased facilities.

Operating 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.

Net cash provided by operating activities for the three months ended March 31, 2022, increased as compared to the corresponding prior year period, primarily due to an increase in cash received on sales of our products and from our commercial collaboration arrangements, including collection of a $100.0 million milestone payment from Ipsen which was partially offset by an increase in cash paid for certain operating expenses resulting in net favorable changes in operating assets and liabilities.

Investing Activities

The changes in cash flows from investing activities primarily relates to the timing of marketable securities investment activity and capital expenditures. Our capital expenditures primarily consist of investments to expand our operations and acquire assets that further our research and development.

Net cash was used in investing activities for the three months ended March 31, 2022 compared to net cash provided by investing activities in the corresponding prior year period. The increase in cash used in investing activities was primarily due to a decrease in cash proceeds from maturities and sales of investments, an increase in purchase of investments which was partially offset by a decrease in capital expenditures.

Financing Activities

The changes in cash flows from financing activities primarily relate to proceeds from employee stock programs and taxes paid related to net share settlement of equity awards.

Net cash was provided by financing activities for the three months ended March 31, 2021, compared to net cash used in financing activities in the corresponding prior year period. The increase in cash provided by financing activities was due to an increase in proceeds received from the issuance of common stock under our equity incentive plans, and lower withholding taxes remitted to the government 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, 2022 from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. In April 2022, the office building (New Premises) associated with our October 2019 build-to-suit lease agreement (Build-to-Suit Lease) was substantially completed. The New Premises is approximately 220,000 square feet and is in Alameda, California, adjacent to our existing corporate headquarters. The Build-to-Suit Lease term is 242 months, includes two five-year options to extend the term of the lease and a one-time option to terminate the lease after 180 months. In addition to the lease payments, we are also responsible for paying operating expenses related to the New Premises. For more information about our Build-to-Suit Lease, and our other contractual obligations see “Note 11. Commitments and contingencies” of the “Notes to Consolidated Financial Statements included Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

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 and/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, 2022, 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 fiscal year ended December 31, 2021, filed with the SEC on February 18, 2022.

Recent Accounting Pronouncements

For a description of the expected impact of recent accounting pronouncements, see “Note 1. Organization and Summary of Significant Accounting Policies” in the “Notes to Condensed Consolidated Financial Statements” included in 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, 2022 have not changed significantly from those described in Item 7A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

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. Patents No. 8,877,776 (salt and polymorphic forms), 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, for CABOMETYX. MSN's initial notice letter did not provide a Paragraph IV certification against U.S. Patents No. 7,579,473 (composition of matter) or 8,497,284 (methods of treatment), each of which is listed in the Orange Book. On October 29, 2019, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of 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 the asserted claims of U.S. Patent No. 8,877,776 are invalid and not infringed. On May 5, 2020, we received notice from MSN that it had amended its ANDA to include additional Paragraph IV certifications. In particular, the ANDA requested approval to market a generic version of CABOMETYX tablets prior to expiration of two previously unasserted CABOMETYX patents: U.S. Patents No. 7,579,473 and 8,497,284. On May 11, 2020, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patents No. 7,579,473 and 8,497,284 arising from MSN's amended ANDA filing with the FDA. Neither of our complaints have alleged infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757. On May 22, 2020, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 7,579,473 and 8,497,284 are 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 (salt and polymorphic forms) is invalid and would not be infringed by MSN if its generic version of CABOMETYX tablets were approved by the FDA. U.S. Patent No. 9,809,549 is not listed in the Orange Book. 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.

On October 1, 2021, pursuant to a stipulation between us and MSN, the Delaware District Court entered an order that (i) MSN's submission of its ANDA constitutes infringement of certain claims relating to U.S. Patents No. 7,579,473 and 8,497,284, if those claims are not found to be invalid, and (ii) upon approval, MSN's commercial manufacture, use, sale or offer for sale within the U.S., and importation into the U.S., of MSN's ANDA product prior to the expiration of U.S. Patents No. 7,579,473 and 8,497,284 would also infringe certain claims of each patent, if those claims are not found to be invalid. Then, on October 12, 2021, pursuant to a separate stipulation between us and MSN, the Delaware District Court entered an order dismissing MSN's counterclaims with respect to U.S. Patent No. 9,809,549. In our complaints, we are seeking, among other relief, an order that the effective date of any FDA approval of MSN's ANDA be a date no earlier than the expiration of all of U.S. Patents No. 7,579,473, 8,497,284 and 8,877,776, the latest of which expires on October 8, 2030, and equitable relief enjoining MSN from infringing these patents. In an effort to streamline the case, the parties have narrowed their assertions. On April 8, 2022, MSN withdrew its validity challenge to U.S. Patent No. 8,877,776. On April 14, 2022, we agreed not to assert U.S. Patent No. 8,497,284 at trial and MSN has, correspondingly, agreed to withdraw its validity challenges to U.S. Patent No. 8,497,284, as well as claims 1-4 and 6-7 of U.S. Patent No. 7,579,473. As a result of this narrowing, the upcoming trial will address two issues: (1) infringement of claims 1 and 2 of the U.S. Patent No. 8,877,776; and (2) validity of claim 5 of the U.S. Patent No. 7,579,473. A three-day bench trial has been scheduled to begin on May 16, 2022.

On January 11, 2022, we received notice from MSN that it had further 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 three previously-unasserted CABOMETYX patents that are now listed in the Orange Book: U.S. Patents No. 11,091,439 (salt and polymorphic forms), 11,091,440 (formulations) and 11,098,015 (methods of treatment). On February 23, 2022, we filed a complaint in the Delaware District Court for patent infringement against MSN asserting infringement of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 (the 2022 MSN ANDA Complaint) arising from MSN's further amendment of its ANDA filing with the FDA. In the 2022 MSN ANDA Complaint, we are seeking, among other remedies, equitable relief enjoining MSN from infringing these patents, as well as an order that the effective date of any FDA approval of MSN's ANDA would be a date no earlier than the expiration of the patents identified in the 2022 MSN ANDA Complaint, the latest of which expires on January 15, 2030. The 2022 MSN ANDA Complaint is a new case against MSN involving Exelixis patents that are different from those asserted in the consolidated Civil Action Nos. 19-02017 and 20-00633 described above. On February 25, 2022, MSN filed its response to the complaint, alleging that the asserted claims of U.S. Patents No. 11,091,439, 11,091,440 and 11,098,015 are invalid and not infringed. A bench trial in connection with the 2022 MSN ANDA Complaint has been scheduled for May 2023.

In May 2021, we received notice letters from Teva regarding an ANDA Teva submitted to the FDA, requesting approval to market a generic version of CABOMETYX tablets. Teva's notice letters included a Paragraph IV certification with respect to our U.S. Patents No. 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 letters did not provide a Paragraph IV certification against any additional CABOMETYX patents. On June 17, 2021, we filed a complaint in the Delaware District Court for patent infringement against Teva, along with Teva Pharmaceutical Industries Limited (Teva Parent), asserting infringement of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757 arising from Teva's ANDA filing with the FDA. On August 27, 2021, Teva filed its answer and counterclaims to the complaint, alleging that the asserted claims of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757 are invalid and not infringed, and on August 23, 2021, we and Teva entered into a stipulation wherein Teva Parent was dismissed without prejudice from this lawsuit and agreed to be bound by any stipulation, judgment, order or decision rendered as to Teva, including any appeals and any order granting preliminary or permanent injunctive relief against Teva. On September 17, 2021, we filed an answer to Teva's counterclaims. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva's ANDA be a date no earlier than the expiration of all of U.S. Patents No. 9,724,342, 10,034,873 and 10,039,757, the latest of which expires on July 9, 2033, and equitable relief enjoining Teva from infringing these patents. On February 8, 2022, the parties filed a stipulation to stay all proceedings, which was granted by the Delaware District Court on February 9, 2022. On February 11, 2022, this case was administratively closed.

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.

In May 2021, we received notice letters from Teva regarding an ANDA Teva submitted to the FDA, requesting approval to market a generic version of CABOMETYX tablets. Teva's notice letters 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 letters did not provide a Paragraph IV certification against any additional CABOMETYX patents. On June 17, 2021, we filed a complaint in the Delaware District Court for patent infringement against Teva, along with Teva Parent, asserting infringement of U.S. Patent Nos. 9,724,342, 10,034,873 and 10,039,757 arising from Teva's ANDA filing with the FDA. On August 27, 2021, Teva filed its answer and counterclaims to the complaint, alleging that the asserted claims of U.S. Patent Nos. 9,724,342, 10,034,873 and 10,039,757 are invalid and not infringed, and on August 23, 2021, we and Teva entered into a stipulation wherein Teva Parent was dismissed without prejudice from this lawsuit and agreed to be bound by any stipulation, judgment, order or decision rendered as to Teva, including any appeals and any order granting preliminary or permanent injunctive relief against Teva. On September 17, 2021, we filed an answer to Teva's counterclaims. We are seeking, among other relief, an order that the effective date of any FDA approval of Teva's ANDA be a date no earlier than the expiration of all of U.S. Patent Nos. 9,724,342, 10,034,873 and 10,039,757, the latest of which expires on July 9, 2033, and equitable relief enjoining Teva from infringing these patents. On February 8, 2022, the parties filed a stipulation to stay all proceedings, which was granted by the Delaware District Court on February 9, 2022. The stipulation and order were filed under seal.

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 dependent upon the commercial success of CABOMETYX in its approved indications and the continued clinical development, regulatory approval, clinical acceptance 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, both in the U.S. and in foreign countries, has come under increasing attention and scrutiny by federal, state and foreign national governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of reducing our revenue or harming our business or reputation.*
- *The timing of the entrance of generic competitors to CABOMETYX and legislative and regulatory action designed to reduce the barriers to the development, approval and adoption of generic drugs in the U.S. could limit the revenue we derive from our products, most notably CABOMETYX, 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 U.S. Food and Drug Administration and comparable foreign regulatory authorities are lengthy, uncertain and subject to change, and may not result in regulatory approvals for additional cabozantinib indications or for 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 discovery and 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 we 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 dependent upon the commercial success of CABOMETYX in its approved indications and the continued clinical development, regulatory approval, clinical acceptance 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 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 CABOMETYX and increase the number of cancer patients who could potentially benefit from this medicine. However, we cannot be certain that the clinical trials we and our collaboration partners are conducting 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 number of labeled indications for which CABOMETYX is approved, or if we or our collaboration partners fail to achieve anticipated product royalties and collaboration milestones, we may need to reduce our operating expenses, access other sources of cash or otherwise modify our business 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 depends 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, foreign and U.S. government healthcare payers such as Medicare and Medicaid, commercial healthcare plans and the medical community. Market acceptance for CABOMETYX could be impacted by 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. If CABOMETYX does not continue to be prescribed broadly for the treatment of patients in its approved 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 and technologies that impair the relative value of our marketed products and any future product candidates.

The biopharmaceutical industry is competitive and characterized by constant technological change and diverse offerings of products, particularly in the area of 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 biopharmaceutical 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. While we have had success in adapting our development strategy for the cabozantinib franchise to address the competitive landscape, including through evaluation of therapies that combine ICIs with other targeted agents, it is uncertain whether current and future clinical trials, including those evaluating cabozantinib in combination with an ICI in NSCLC and mCRPC,

will lead to regulatory approvals, or whether physicians will prescribe regimens containing cabozantinib instead of competing product combinations in approved indications.

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 our 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 biopharmaceutical companies seeking to build out and maintain their commercial organizations, as well as larger biopharmaceutical 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 foreign and U.S. 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, or alternatively for patients who rely on our co-pay assistance program, implement co-pay accumulators or maximizers that exempt such co-pay assistance from patient deductibles, which has increased and could further increase the costs of our co-pay assistance program or cause patients to abandon CABOMETYX or COMETRIQ therapy due to higher out-of-pocket costs. If third-party payers do not provide or increase limitations on coverage or reimbursement for CABOMETYX or COMETRIQ, our revenues and results of operations may 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, it is possible that the PPACA will be subject to additional judicial or legislative challenges in the future, which may have a material adverse impact on our business, financial condition and results of operations, and we

cannot predict how future healthcare reform measures of the Biden Administration and 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 Pricing Program through the PPACA (the 340B Program) has increased the number of purchasers who are eligible for significant discounts on branded drugs, including our marketed products. Because we participate in the 340B Program to sell a portion of our marketed products, changes in the administration of the program could have a material adverse impact on our revenues, including the implementation of the program’s Administrative Dispute Resolution Process, which is in part intended to resolve claims by covered entities that manufacturers have overcharged them for covered outpatient drugs. A federal court has preliminarily enjoined the 340B Administrative Dispute Resolution Process with respect to the plaintiff manufacturer in that specific challenge, and other legal challenges are ongoing. The Office of Management and Budget initiated review of a new proposed rule titled “340B Drug Pricing Program; Administrative Dispute Resolution” in November 2021. In addition, there is ongoing litigation regarding the legality of contract pharmacy arrangements under the 340B Program, which may affect the way in which manufacturers are required to extend discounts to covered entities through contract pharmacies. Due to general uncertainty with respect to this litigation and 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 drug prices to the prices of drugs in other countries); reform the structure and financing of Medicare Part D pharmaceutical benefits; implement additional data collection and transparency reporting regarding drug pricing, rebates, fees and other remuneration provided by drug manufacturers; enable the government to negotiate prices under Medicare; revise rules associated with the calculation of average manufacturer price and best price under Medicaid; 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 revise the rebate methodology under the Medicaid Drug Rebate Program. For instance, President Biden issued an executive order in July 2021 supporting legislation to enact some of these drug pricing reforms, and in response, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices in September 2021 with specific legislative and administrative policies that Congress could enact to help improve affordability of and access to prescription drugs. 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 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 biotherapeutic 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 and accessibility, as well as post-marketing assessments of the added value of CABOMETYX and COMETRIQ as compared to existing treatments, could influence the prices paid for and net revenues we realize from CABOMETYX and COMETRIQ, or the indications for which we are able to obtain reimbursement, which would result in lower license revenues to us. Upcoming legislative and policy changes in the EU are aimed at increasing cooperation between the EU Member States. Such initiatives, particularly the Regulation on Health Technology Assessment adopted in December 2021, may further impact the price and reimbursement status of CABOMETYX and COMETRIQ in the future.

The timing of the entrance of generic competitors to CABOMETYX and legislative and regulatory action designed to reduce barriers to the development, approval and adoption of generic drugs in the U.S. could limit the revenue we derive from our products, most notably CABOMETYX, 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—Abbreviated FDA Approval Pathways and Generic Products" in our Annual Report on Form 10-K for the fiscal year ended December 31, 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, and we have subsequently filed patent lawsuits against both companies. For a more detailed discussion of these litigation matters, 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 would likely decrease our revenues derived from the U.S. sales of CABOMETYX and thereby materially harm our business, financial condition and results of operations. There are also equivalent procedures in the EU permitting authorization of generic versions and biosimilars of medicinal products authorized in the EU once related data and market exclusivity periods have expired.

The U.S. federal government has also taken numerous legislative and regulatory actions to expedite the development and approval of generic drugs and biosimilars. Both Congress and the FDA are considering, and have enacted, 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 Ensuring Innovation Act, enacted in April 2021,

amended the FDA's statutory authority for granting new chemical entity (NCE) exclusivity to reflect the agency's existing regulations and longstanding interpretation that award NCE exclusivity based on a drug's active moiety, as opposed to its active ingredient, which is intended to limit the applicability of NCE exclusivity, thereby potentially facilitating generic competition. 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. In addition, the Further Consolidated Appropriations Act, 2020, which incorporated the framework from the Creating and Restoring Equal Access To Equivalent Samples (CREATES) legislation, purports to promote competition in the market for drugs and biotherapeutic products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biotherapeutic products, including by allowing ANDA, 505(b)(2) NDA or biosimilar developers to obtain access to branded drug and biotherapeutic 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 the Civil Monetary Penalties Law;
- 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, and also impact our current and future business arrangements with third parties, including various healthcare entities. 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 through a Corporate Integrity Agreement or other monitoring agreement, 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 or investigation 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 HHS 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. Moreover, in December 2020, the Centers for Medicare and Medicaid Services finalized changes to Medicaid Drug Rebate Program pricing calculations regarding the provision of co-payment assistance to patients that may be impacted by private insurer accumulator programs. Although this rule is subject to litigation, if sustained, the rule could affect the amount of rebates owed under the Medicaid program or otherwise limit our ability to support our patient co-pay assistance program. 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 in the U.S. and other jurisdictions around the world. 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 the California Privacy Rights Act (CPRA), which will be operational in most key respects on January 1, 2023. Similar legislative proposals have passed or are being advanced in other states, and Congress is also considering additional federal privacy legislation. In addition, most healthcare professionals and facilities are subject to privacy and security requirements under HIPAA with respect to our clinical and commercial activities. 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, in the EU, 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, an increase in our cost of doing business and questions concerning the validity of our data processing activities, including clinical trials.

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 a product candidate or of an approved product for a new 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 in new indications or of new product candidates. These events 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 clinical 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 extended timelines to provide for collaboration on clinical development planning, 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
- reduced staffing or shortages in laboratory supplies and other resources necessary to complete the trials;
- 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, variations, 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.

The ongoing Russo-Ukrainian War could have a modest impact on our clinical development operations, particularly with respect to patient recruitment, potentially delaying our ability to complete enrollment in a timely manner. In addition, this conflict has had and may continue to have an adverse impact on the ability of clinical sites and their patients to adhere to trial protocols for in-office clinical visits and other procedures, our ability to supply clinical sites with cabozantinib or other study drugs and to pay clinical sites and investigators for work performed, as well as our ability to collect data and conduct site monitoring visits, all of which could undermine the data quality for patients enrolled at these clinical sites. The need to shift enrollment of patients away from these clinical sites, or potentially to replace a significant number of patients in affected territories should investigators be unable to continue treating and monitoring them, could further impact our anticipated timelines for completing the trials and achieving clinical endpoints.

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 otherwise 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: the 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, uncertain and subject to change, and may not result in regulatory approvals for additional cabozantinib indications or for 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 regulatory 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 comparable 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. For example, the FDA launched Project Optimus in 2021 as an initiative to reform the dose optimization and dose selection paradigm in oncology drug development, which was driven by the FDA's concerns that the current paradigm for dose selection may result in doses and schedules of molecularly targeted therapies that are inadequately characterized before initiating pivotal trials. Through collaboration with the biopharmaceutical industry, academia and other stakeholders, the FDA's goal for this initiative is to advance an oncology dose-finding and dose optimization paradigm that emphasizes dose selections that maximize efficacy as well as safety and tolerability. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies pre- or post-approval, and the FDA also continues to develop and finalize guidance documents and implement initiatives regarding the development and clinical research of oncology product candidates. Recently, in part due to questions raised by the process underlying the approval of the Alzheimer's disease drug Aduhelm®, government authorities and other stakeholders have been scrutinizing the accelerated approval pathway, with some stakeholders advocating for reforms. Even prior to the Aduhelm approval, FDA has held Oncologic Drugs Advisory Committee meetings to discuss accelerated approvals for which confirmatory trials have not verified clinical benefit. Such scrutiny, among other factors, has resulted in voluntary withdrawals of certain products and indications approved on an accelerated basis. Moreover, also spurred by the Aduhelm controversy, the HHS Office of Inspector General has initiated an assessment of how the FDA implements the accelerated approval pathway. In addition, members of Congress have introduced proposed legislation to revise the statutory accelerated approval pathway, including with respect to the FDA's ability to rapidly withdraw products and indications for which effectiveness is not confirmed in post-marketing studies. At this time, it is not clear what impact, if any, these developments may have on the statutory accelerated approval pathway or our business, financial condition and results of operations.

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-marketing 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. 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 governing FDA or foreign regulatory approval processes that may be enacted or executed could have a material adverse impact on our business, financial condition and results of operations.

We may be unable to expand our discovery and 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 $68.6 million for the three months ended March 31, 2022 and $231.1 million for the fiscal year ended December 31, 2021, 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 development, 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 and business development activities, both for the cabozantinib franchise and our earlier-stage product candidates, as well as our general business expansion plans. Our expected future expenses in particular may also be increased by inflationary pressures, whether resulting from the effects of the ongoing Russo-Ukrainian War or the COVID-19 pandemic or otherwise, which could increase the costs of outside services, labor, raw materials and finished drug product. 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 strategic transactions 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 our earlier-stage product candidates, 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. 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 we 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 biopharmaceutical companies 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 negligence or other insufficient 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, 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 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 that 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 otherwise disadvantage healthcare products made by foreign competitors, as well as 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, third-party contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if the third parties must be replaced or if the quality or accuracy of the data they generate or provide is compromised due to their failure to adhere to our clinical 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 beyond currently approved indications or obtain regulatory approval for our other product candidates. 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 or distribution facilities 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. Although we have not yet experienced significant production delays or seen significant impairment to our supply chain as a result of the COVID-19 pandemic or the ongoing Russo-Ukrainian War, our third-party contract manufacturers, distributors and suppliers could experience operational delays due to facility closures and other hardships as a result of these types of global events, 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 increased demand for such services from other companies or by other external factors, such as reduced capacity to perform services, 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. 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 future 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. They may also be negatively impacted by the decisions of foreign courts, which could limit the protection contemplated by the original regulatory approval and our ability to thwart the development of competing products that might otherwise have been determined to infringe our intellectual property rights. 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 the EU, have compulsory licensing laws based on related EU rules, 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 Russian Federation has and may further limit protections on patents originating from “unfriendly countries” (including the U.S.) in response to sanctions relating to the ongoing Russo-Ukrainian War, and in general, 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 also rely on trade secret protection for some of our confidential and proprietary information, and we are taking security measures to protect our proprietary information and trade secrets, particularly in light of recent instances of data loss and misappropriation of intellectual property in the biopharmaceutical industry. However, these measures may not provide adequate protection, and while we seek to protect our proprietary information by entering into confidentiality agreements with employees, partners and consultants, as well as maintain cybersecurity protocols within our information technology infrastructure, 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 with respect to 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 the access to treatment sites that is necessary to monitor clinical study progress and administration. As the COVID-19 pandemic continues to have a significant presence in various parts of the world, particularly with the spread of the Omicron and other SARS-CoV-2 variants and the potential emergence of new variants that may prove especially contagious or virulent, 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, including staffing and materials shortages 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 further delay some of our clinical trial plans or may require certain trials to be temporarily suspended. 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. Depending upon the duration and severity of the COVID-19 pandemic, we could also experience delays in planning and conducting new clinical trials of the investigative product candidates entering and advancing through our development pipeline, which could increase the operating expenses associated with these trials and adversely affect their timelines for completion and ultimately our ability to obtain regulatory approvals.

Both drug discovery work in our laboratories and outsourced drug discovery activities have fully resumed following temporary suspensions during the early days of the COVID-19 pandemic; however, we may be unable to maximize the potential of these programs due to the imposition of increased safety protocols, and should the effects of the COVID-19 pandemic become more severe, we may have to again scale back or suspend activities in the future. We are also reliant on laboratory materials manufactured and distributed from areas impacted by both the COVID-19 pandemic and other natural

disasters, for which supply has become limited. If we are unable to obtain the requisite materials to conduct our planned drug discovery activities, we may be required to redirect the focus of, or even suspend, such activities. 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.

These continuing or future effects of the COVID-19 pandemic 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 continue 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. 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. Such liability may exceed our insurance coverage and our total assets, and 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 strategic transactions;
- 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 biopharmaceutical 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.

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, policies governing foreign trade and healthcare spending and delivery, or the ongoing Russo-Ukrainian War, 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 initiated. 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	Restated Certificate of Incorporation of Exelixis, Inc.	10-Q	000-30235	3.1	8/5/2021	
3.2	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	3/3/2021	
10.1*	Collaboration and License Agreement dated January 30, 2017, by and between Exelixis, Inc. and Takeda Pharmaceutical Company Limited					X
10.2*	Second Amendment dated May 7, 2019, to Collaboration and License Agreement dated January 30, 2017, by and between Exelixis, Inc. and Takeda Pharmaceutical Company Limited					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

* 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 10, 2022
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 January 30, 2017 (the "**Effective Date**"), by and between **Exelixis, Inc.**, a Delaware company having an address at 210 East Grand Avenue, South San Francisco, CA 94080, USA ("**Exelixis**") and Takeda Pharmaceutical Company Limited, a Japanese corporation with principal offices located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, JAPAN ("**Collaborator**"). Exelixis and Collaborator may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

Recitals

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

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

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

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

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

Agreement

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

1. Definitions

1.1 "**Affiliate**" means, subject to the final sentence of this paragraph, with respect to any party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such party, but for only so long as such control exists. As used in this Section 1.1, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance; or (b) direct or indirect

beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity. For the avoidance of any doubt, neither [*] nor [*] shall constitute an Affiliate of Collaborator.

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

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

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

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

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

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

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

1.9 "**cGLP**" means the current good laboratory practice standards promulgated or endorsed by the FDA, as defined in U.S. 21 C.F.R. Part 58 (or such other comparable regulatory standards in jurisdictions outside the U.S.), as they may be updated from time to time.

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

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

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

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

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

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

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

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

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

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

(a) [*]; and

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

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

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

1.22 "**Confidential Information**" means all Know-How and other proprietary scientific, marketing, financial, or commercial information or data that is generated by or on behalf of a Party or its Affiliates or which one Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing, or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs, or formulae in relation to this Agreement; provided that all Exelixis Technology will be deemed Exelixis' Confidential Information, all Collaborator Technology will be deemed Collaborator's Confidential Information, and all Joint Inventions and Joint Patents will be deemed both Parties' Confidential Information. Confidential Information shall include: (a) the terms and conditions of this Agreement, and (b) Confidential Information disclosed by either Party pursuant to the Confidentiality Agreement.

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

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

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

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

1.27 "**Development Costs**" means the costs incurred by a Party or for its account, during the Term and pursuant to this Agreement, that are specifically directed (or reasonably allocable) to the Development of a Product. The Development Costs shall include amounts that a Party pays to Third Parties involved in the Development of a Product (at cost, and excluding any Third Party Royalties), and all internal costs (calculated on an FTE basis at the then-current FTE Rate) and reasonable out-of-pocket costs incurred by or on account of a Party in performing Development work in accordance with the GDP. Development Costs shall also include [*]. For clarity, [*].

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

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

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

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

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

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

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

1.35 "**Export Control Laws**" means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

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

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

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

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

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

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

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

1.43 "**FTE Rate**" means, with respect to Exelixis' personnel, an initial rate of [*] U.S. Dollars ($[*]) per FTE per year, which rate shall apply through December 31, 2017.

Thereafter, the FTE Rate for Exelixis' personnel shall be changed annually on a Calendar Year basis to reflect any year-to-year percentage increase or decrease (as the case may be) in the Consumer Price Index for All Urban Consumers for the U.S., as published by the U.S. Department of Labor, Bureau of Labor Statistics ("**CPI**"). With respect to Collaborator's personnel, "FTE Rate" means a reasonable rate in Japanese yen reasonably determined by Collaborator based on Collaborator's actual, fully-burdened costs for Collaborative Work on a case-by-case basis, provided that Collaborator shall provide Exelixis with supporting documentation for each such determination.

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

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

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

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

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

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

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

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

the Field. Know-How excludes Patents and manufacturing know-how of the Compound or Product.

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

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

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

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

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

(a) normal and customary trade and quantity discounts actually allowed and properly taken directly with respect to sales of such Product (provided that such discounts are not applied disproportionately to such Product when compared to the other products of Collaborator or its Affiliate or Sublicensee, as applicable);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.68 "**Regulatory Authority**" means any Governmental Authority that has responsibility in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a given jurisdiction, including the FDA and

MHLW, or any successor agency of the foregoing having regulatory jurisdiction over the manufacture, distribution, and sale of drugs in the Collaborator Territory, and any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Defined Terms	**Section**
Acquisition Transaction	16.8(b)
Alliance Manager	3.7
Allowable Increases	4.5(a)
Auditor	9.4
Beneficial Party	8.2(d)
Budget Cap	4.5(a)
Claim	12.3
Collaborative Work	4.5(a)
Collaborator Data	10.1(a)
Collaborator Indemnitee	12.1
Collaborator Local Development Work	4.5(c)
Commercialization Plan	6.2
Competing Program	2.8(a)
Compound Invention	10.1(b)(i)
Development Budget	4.2(b)
Developing Party	4.3
Disputed Matter	15.2
Divest	2.8(b)
Exelixis Data	10.1(a)
Exelixis Entity	16.8(a)(i)(1)
Exelixis Indemnitee	12.2
Exelixis Local Development Work	4.5(c)
First Full Calendar Year	6.3(b)

First Generic Entry	2.8(a)
Global Development Plan or GDP	4.2(a)
Indemnitee	12.3
Indemnitor	12.3
Independent Work	4.3
Independent Work Cost	8.2(b)
Injunctive Relief	15.3(b)
Joint Commercialization Committee or JCC	3.3
Joint Development Committee or JDC	3.2
Joint Executive Committee or JEC	3.1
Joint Inventions	10.1(b)(ii)
Joint Patents	10.1(b)(ii)
Local Regulatory Requirement	3.5(b)(i)(2)
Losses	12.1
Materials	4.14
Minimum Commercial Performance	6.3(b)
Minimum Commercial Performance Period	6.3(b)
Newly-Proposed Development	4.3
Non-Developing Party	4.3
PV Costs	5.5(c)
Pharmacovigilance Agreement	5.5(a)
Previously Achieved Sales Milestone	8.4(a)
Product Infringement	10.4(a)
Product Marks	10.8(a)
Promotional Materials	6.4(c)
Proposal	4.3
Quality Agreement	7.1
Recall	5.9
Regulatory Meeting	5.3
Remaining Royalty Term	8.5(d)
Responding Party	13.4(a)
Royalty Term	8.5(c)
Rules	15.3(a)
Sole Inventions	10.1(b)(ii)
Standstill Period	16.8(a)
Submitting Party	13.4(a)

[*] = 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.

Sunshine Reporting Laws	5.10
Supply Agreement	7.1
Supply Contacts	3.8
Term	14.1(a)
Unaffiliated Third Party	2.8(a)
Withholding Tax Action	9.3(c)

2. Grant of Licenses

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

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

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

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

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

hereunder without the prior written consent of Exelixis; provided, however, that Collaborator shall impose on each such contractor the same obligations that Collaborator undertakes hereunder and Collaborator shall remain responsible to Exelixis for the performance of such obligations by each such contractor.

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

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

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

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

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

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

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

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

2.5 No Implied Licenses; Negative Covenant. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Patents, Know-How, or other intellectual property owned or controlled by the other Party. Neither Party shall, nor shall it permit any of its Affiliates or sublicensees to, practice any Patents or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement. Without limitation of the foregoing, each Party acknowledges the restrictions on its activities set forth in Section 4.13 and Collaborator agrees that such activities are outside the scope of the licenses granted to it herein.

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

2.7 Third Party Licenses.

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

(b) Collaborator shall promptly notify Exelixis if it becomes aware of any Third Party's Patents that are necessary or reasonably useful to Develop, make, have made, use, sell, offer for sale, import or Commercialize the Compound and Products in the Field in the Collaborator Territory, and shall give Exelixis the first right to negotiate and obtain a license

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

2.8 Exclusivity.

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

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

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

(ii) if such transaction arises with respect to [*], then such assignee or new Affiliate (as the case may be; in either case, referred to as [*] for the remainder of this Section 2.8(b)(ii)) shall continue to Develop and Commercialize the Product [*] that assumes as if the Competing Program was not acquired, provided that, within [*] after the closing of such transaction, [*] shall either: (a) Divest the Competing Program to a Third Party, or (b) discontinue the Competing Program. For clarity, if the closing of such transaction occurs after the earlier of 2.8(a)(i)(1) or 2.8(a)(i)(2), [*] may continue the development of such Competing Program [*], but shall in no event be permitted to commercialize such Competing Program in the Competitive Field in the Collaborator Territory until two (2) years after the First Generic Entry, as set forth in Section 2.8(a)(ii). For the avoidance of any doubt, during such [*] period, [*] shall continue to fulfill its obligations under this Agreement in all respects, shall conduct

Competing Program activities independently of the activities pursuant to this Agreement, shall not use any [*] in the conduct of the Competing Program, and shall not initiate or launch any new Competing Program activities. Notwithstanding the foregoing, in the event that [*] reasonably anticipates that it will require more than [*] to complete any then-ongoing clinical trials or studies with respect to the Competing Program, then [*] shall notify Exelixis via the JEC and the JEC shall discuss and determine in good faith any necessary extension to such [*] period to permit [*] solely to complete and not to interrupt such ongoing clinical trials and studies with respect to the Competing Program, and [*] shall not withhold its consent to any such necessary extension. For clarity, if [*] completely winds down the Competing Program within such [*] time period plus the period of time of the extension, if any, [*] shall be allowed to Divest the Competing Program later, provided that it does not restart any Competing Program activities. For the purpose of this Section 2.8(b)(ii), an "ongoing clinical trial or study" shall be any clinical trial or study for which [*] as of the closing of such transaction.

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

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

2.9 Authorized Generics and Off Patent Products.

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

(b) Off Patent Products. The Parties acknowledge that it may be in the Parties' mutual interest and wishes to continue to commercialize the Product for patients in the Collaborator Territory by using Exelixis supplied API, Compound, or Product even after the [*] for such Product. If Collaborator desires to purchase the API, Compound, and/or Product of the

Collaborator Territory after the [*] for such Product, Collaborator shall notify Exelixis up to [*] prior to the expiration of the [*] and the Parties shall discuss in good faith with the intent to determine commercially reasonable terms and conditions for the continued supply of the API, Compound, and/or Product (in the form then-currently supplied to Collaborator by Exelixis and which supply price shall include a reasonable margin) and a license under the Product Marks for use in connection with the Commercialization of the Product.

3. Governance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(h) perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Commercialization of Products, including endeavoring to

resolve any disputes between the Parties arising from the deliberations of the JCC, or as otherwise directed by the JEC.

3.4 Committee Membership and Meetings.

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

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

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

3.5 Decision-Making.

(a) All decisions of each Committee shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before a Committee, the representatives of the Parties cannot reach an agreement as to such matter within [*] after such matter was brought to such Committee for resolution, then, except as provided in Section 3.5(c), if such disagreement arose within the JDC or JCC, it shall be referred to the JEC for resolution. If the JEC cannot resolve such matter within [*], or if the disagreement first arose within the JEC, then either Party at any time may refer such issue to the Executive Officers for resolution.

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

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

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

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

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

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

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

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

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

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

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

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

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

4. Development

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

4.2 Development Plan.

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

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

(c) If upon the determination by the JDC, any modification to the then-current GDP, including any non-clinical or Clinical Trials not included in the GDP, (i) is required in order to obtain and/or maintain MAA Approval for a Product in the Collaborator Territory or in one or more of the countries of the Exelixis Territory, (ii) is otherwise recommended or suggested by the PMDA in the Collaborator Territory or the FDA or other Regulatory Authority in the Exelixis Territory, (iii) is required by any local or regional IRB/ethics committee or (iv) is reasonably deemed necessary to protect patient safety, then the JDC shall prepare an amendment to the GDP reflecting such required, recommended or suggested modification, including associated Development Budget. The costs of such additional studies shall be borne by the Parties as provided in Section 4.5(a).

4.3 Independent Work. If either Party is interested in pursuing additional Development work on a Product (the "**Developing Party**") for the benefit of the Exelixis Territory (in the case of Exelixis) or the Collaborator Territory (in the case of Collaborator) beyond what is set forth in the then-current GDP, then such Party shall provide the other Party with a written detailed plan and budget for such additional work (the "**Proposal**"). Within [*]

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

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

4.5 Development Cost.

(a) Collaborative Work Cost. Exelixis shall be responsible for eighty percent (80%) and Collaborator shall be responsible for twenty percent (20%) of all Development Costs for any Development activities (including Clinical Trials) set forth in the GDP other than Independent Work, Collaborator Local Development Work and/or Exelixis Local Development Work (the "**Collaborative Work**"). For the avoidance of any doubt, such Development Costs with respect to the Collaborative Work shall include work performed by temporary workers and contractors on applicable activities and all Allowable Increases. For the purpose of this Section 4.5(a), "**Allowable Increases**" are defined as increased Development Costs in connection with the Collaborative Work resulting from (i) changes in study design after the Effective Date that are approved by the JDC [*] (up to the amount of a mutually-agreed budget increase), (ii) changes in regulatory requirements arising after the Effective Date (including changes required or recommended by Regulatory Authorities, but excluding changes required or recommended specifically by a Regulatory Authority of the Exelixis Territory solely for the benefit of the Exelixis Territory), or (iii) extensions in the duration of Clinical Trials

resulting from a lower than anticipated patient accrual rate, rate of clinical events, or higher rates of survival. The Parties' foregoing Development Cost obligations with respect to the Collaborative Work (including Allowable Increases, if any) are subject to a maximum payment obligation of [*] of the amount specified in the Development Budget (the "**Budget Cap**"). For clarification, notwithstanding Section 3.2(f), in the event that the Collaborative Work is conducted in accordance with the GDP and within the Budget Cap, no amendment of the Development Budget shall be required. In the event that Development Costs are expected or anticipated to exceed the Budget Cap, the Party conducting the applicable Clinical Trial shall notify the other Party and the JDC shall meet to discuss amending the Development Budget.

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

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

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

4.7 Data Exchange and Use.

(a) General. In addition to its adverse event and Safety Data reporting obligations pursuant to Section 5.5, each Party shall promptly provide the other Party with (i)

[*] status reports on trial recruitment and other metrics consistent with the performing Party's internal reporting for clinical studies and Development activities, provided however that in case of unexpected events that may have any impact on safety, (such case will be elaborated and defined in Pharmacovigilance Agreement), each Party shall inform the other Party within [*] from knowledge of the occurrence of such event; (ii) supporting documentation (e.g. protocols, case report forms, analysis plans, etc.); (iii) preliminary and final Data, and interim, preliminary, and final results and reports; and (iv) output from advisory committees and investigator meetings, any and all such documentation generated by each Party (including by any Sublicensee or licensee) from its Development activities under this Agreement as such documentation could reasonably be deemed to affect the Development or Commercialization activities of the Product in each Party's territory. As time may be of the essence, each Party shall collaborate in good faith in the exchange of any such Data set forth in this Section within [*] of receipt. The Parties shall cooperate on a secure website to facilitate the sharing of reports, Data, and other information on a routine basis. Except as set forth in Section 4.7(b) below, each Party shall have the right to use and reference, without additional consideration, any and all Data generated by or on behalf of the other Party (including by any Sublicensee or other licensee) under this Agreement for obtaining and maintaining Regulatory Approval for the Products and otherwise Commercializing the Products in its territory in accordance with the terms of this Agreement. For clarity, this Section 4.7(a) shall apply to any and all Data generated in the Development under the GDP, including Independent Work (but subject to Section 4.7(b) below), Exelixis Local Development Work, and Collaborator Local Development Work. Notwithstanding the foregoing, should either Party fail to obtain such use and reference rights entirely from any Sublicensee or other licensee, such Party shall not have the right to grant use and access or rights to such Sublicensee or other licensee to any corresponding documentation for which such Party failed to obtain such right listed in this Section 4.7(a) generated by or on behalf of the other Party.

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

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

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

4.10 Development Records. Each Party shall maintain complete, current, and accurate records of all Development activities conducted by it hereunder, and all Data and other information resulting from such activities. Such records shall fully and properly reflect all work

done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all non-clinical studies and Clinical Trials in formal written study reports according to Applicable Laws and national and international guidelines (e.g., ICH, cGCP, cGLP, and cGMP).

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

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

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

4.14 Materials Transfer. In order to facilitate the Development activities contemplated by this Agreement, either Party may provide to the other Party certain biological materials or chemical compounds Controlled by the supplying Party (collectively, "**Materials**") for use by the other Party in furtherance of such Development activities. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party will remain the sole property of the supplying Party, will be used only in furtherance of the Development activities conducted in accordance with this Agreement, will not be used or delivered to or for the benefit of any Third Party, except to subcontractors permitted in Section 4.12, without the prior written consent of the supplying Party, and will be used in compliance with all Applicable Laws. The Materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. Except as expressly set forth in this Agreement, THE MATERIALS ARE PROVIDED "AS IS" AND

WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

5. Regulatory Activities

5.1 Regulatory Responsibilities.

(a) General.

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

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

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

(b) Transfer of Regulatory Filings. Exelixis shall provide, promptly after the execution of this Agreement, to Collaborator a copy of all the IND for the Product for the Collaborator Territory submitted to the PMDA, which IND the Parties acknowledge is, as of the Effective Date, closed and inactive in the Collaborator Territory. Collaborator shall have a right to use and/or reference such IND in connection with Collaborator's Development and regulatory activities under this Agreement.

5.2 Regulatory Information Sharing. To the extent that such Regulatory Filings that relate to the activities in the requesting Party's territory, each Party shall, upon the other Party's reasonable request, promptly provide the other Party (but in no event more than [*]) with copies of Regulatory Filings prepared (including any drafts and supporting information), submitted or received by such Party in the Exelixis Territory including the U.S. and the

Collaborator Territory pertaining to the Compound and Products, and such other Party shall have the right to review and comment on drafts of such Regulatory Filings, provided that such review and comment shall not delay the submission of any Regulatory Filings. The sharing of Regulatory Filings shall include any communications/correspondence with the Regulatory Authority regarding label changes, IND annual reports and cover letters, and documents related to regulatory milestones and dates (e.g., submissions and validations). If any Regulatory Filing to be provided under this Section 5.2 was originally created in a language other than the English language, then at the receiving Party's request and to the extent already existing and readily available, the providing Party shall provide an English translation along with the original document to the receiving Party. The Parties acknowledge that it is their intent to collaborate in good faith in the exchange of such Regulatory communications including with any Sublicensee or other Exelixis licensee. Each of Collaborator and Exelixis shall reasonably endeavor to grant access and rights for the other Party to use any such communications with any Regulatory Authority generated by or on behalf of any Sublicensee or other Exelixis licensee, respectively. For clarity, a Party's provision to the other Party of copies of Regulatory Filings prepared, submitted, or received in each Party's territory is expressly conditioned upon the receiving Party granting to the providing Party the right to share with the providing Party's own licensee for its territory copies of any and all Regulatory Filings prepared, submitted, or received by the receiving Party in its territory. Should either Party fail to obtain such access and rights from any Sublicensee or Exelixis licensee, such Party shall not have the right to grant access or rights to such Sublicensee or other Exelixis licensee to any such communications with any Regulatory Authority generated by or on behalf of the other Party.

5.3 Meetings with Regulatory Authorities. On a current and ongoing basis, each Party shall provide the other Party with a list and schedule of any significant in-person meeting or teleconference with the Regulatory Authorities (or related advisory committees) in the Collaborator Territory planned for the next [*] that relates to the Development of the Compound and Products under the GDP in the Collaborator Territory (each, a "**Regulatory Meeting**"). In addition, each Party shall notify the other Party as soon as reasonably practicable if such Party becomes aware of any additional Regulatory Meetings that become scheduled for such [*] and will keep the other Party informed of any significant interface or communication with any Regulatory Authority which is reasonably expected to affect efforts to obtain Regulatory Approval for the Product in its respective territory. Collaborator shall be solely responsible for any communications with the Regulatory Authorities occurring or required in connection with performing its regulatory responsibilities set forth in this Article 5 with respect to the Product in the Collaborator Territory, and Exelixis shall have the right to provide input in preparation for all Regulatory Meetings and the right, but not the obligation, to have its representatives attend (but, unless otherwise requested by Collaborator, not participate in) the Regulatory Meetings. Collaborator shall have these same rights with respect to any such Regulatory Meetings in the Collaborator Territory before such Regulatory Filings are transferred to Collaborator under Section 5.1(b).

5.4 Regulatory Inspections. Collaborator shall permit the Regulatory Authority(ies) in the Exelixis Territory to conduct inspections of Collaborator, its Affiliates, Sublicensees, or subcontractors (including Clinical Trial sites) relating to Product Development under the GDP or the Finished Manufacture of the Finished Product, and shall ensure that such Affiliates, Sublicensees, and subcontractors permit such inspections. In addition, Collaborator shall promptly notify Exelixis of any such inspection and shall supply Exelixis with all information

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

5.5 Pharmacovigilance and Adverse Event Reporting.

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

(b) Global Safety Database. Exelixis has established and shall continue to hold, at its expense, the Product global safety database, and shall maintain such global safety database for so long as such Product is under Development and/or Commercialization hereunder. Exelixis will ensure that each Party is able to access the Safety Data, if necessary indirectly, from the global safety database in order to meet legal and regulatory obligations. For the Collaborator Territory, the Parties will agree on data cut points for periodic aggregate safety reports, Exelixis will author such reports, including the integrated data sets, the Parties will jointly review and approve such reports, and Collaborator will generate final versions of the reports for submission in accordance with regulatory requirements in the Collaborator Territory. If the PMDA requires any additional reports, Collaborator shall prepare such reports for submission to the PMDA, consulting with Exelixis as practicable and appropriate and, upon Exelixis' reasonable request, providing to Exelixis a copy (in English) of any such report.

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

(d) PV Governance. The JDC shall establish a safety subcommittee and all Safety Data, including adverse event reports, shall be submitted to such safety subcommittee and Exelixis concurrently so that Exelixis may update the global safety database accordingly. Such safety subcommittee shall coordinate with respect to any Safety Data reporting for the Product to Regulatory Authorities in the Collaborator Territory, but Collaborator shall be primarily

responsible for (i) reporting quality complaints, adverse events, and Safety Data related to the Products, and all case processing of adverse events, to applicable Regulatory Authorities in the Collaborator Territory, and (ii) responding to safety issues and to all requests of Regulatory Authorities in the Collaborator Territory related to the Products, in each case at its own expense. Collaborator shall have the right to use, at its own expense, a safety database owned by Collaborator for the purpose of tracking and reporting quality complaints, adverse events, and Safety Data related to the Products in the Collaborator Territory; provided, however, that such right shall not relieve Collaborator of its obligation to communicate all such information directly to the safety subcommittee and Exelixis. Each Party agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, licensees, and sublicensees to comply with such obligations.

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

5.7 Notification of Threatened Action. Each Party shall notify the other Party within [*] of any information it receives regarding any threatened or pending action, inspection, or communication by any Regulatory Authority, which may affect the safety or efficacy claims of any Product or the continued Development or Commercialization of any Product. Upon receipt of such information, the Parties shall promptly consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

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

5.9 Recalls. In the event that a recall, withdrawal, or correction (including the dissemination of relevant information) of any Product in a Party's territory is required by a Regulatory Authority of competent jurisdiction, or if any Regulatory Authority requires or advises either Party or such Party's Affiliates or sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of such Product in a Party's territory, or if a recall, withdraw, or correction of a Product in its territory is deemed advisable by such Party in its sole discretion, such Party shall so notify the other Party no later than [*] in advance of the earlier of (i) initiation of a recall, withdrawal, or correction; or (ii) the submission of plans for such an action to a Regulatory Authority. Any such recall, withdrawal, correction, or dissemination of information (e.g., "Dear Doctor" letter) shall be referred to herein as a "**Recall**". Promptly after being notified of a Recall, each Party shall provide the other Party with such assistance in connection with such Recall as may be reasonably requested by such other Party. All costs and expenses in connection with a Recall in a Party's territory shall be paid by such Party, including

without limitation the costs and expenses related to the dissemination of relevant information. Each Party shall handle exclusively the organization and implementation of all Recalls of Products in its territory. Notwithstanding the foregoing, any Recall related to the manufacture and supply of the Product by Exelixis to Collaborator shall be governed by the terms and conditions of the Parties' applicable Supply Agreement and the Quality Agreement.

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

6. Commercialization

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

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

6.3 Diligence.

(a) General. During the Term, Collaborator shall use Commercially Reasonable Efforts to Commercialize the Products for all indications that have received or will receive Regulatory Approval throughout the Collaborator Territory. In addition, and without

limitation of the foregoing, Collaborator shall, as soon as possible following each MAA Approval(s), launch the Product for such indication and obtain all necessary Price and Reimbursement Approvals. Thereafter, Collaborator shall utilize Commercially Reasonable Efforts in the ongoing support for the Product in the Collaborator Territory.

(b) Minimum Commercial Performance. In addition to the foregoing general commitments, Collaborator shall also achieve for the first six (6) full Calendar Years following the First Commercial Sale of the Product in the Collaborator Territory (the "**Minimum Commercial Performance Period**") (i) a minimum annual sale volume based on the aggregate sales forecast for the Collaborator Territory, and (ii) minimum annual promotional and sales force requirements for the Collaborator Territory, for each Calendar Year as set forth in the table below ((i) and (ii) collectively, the "**Minimum Commercial Performance**"). The Minimum Commercial Performance for the First Full Calendar Year shall be determined by [*], and set forth in the first Commercialization Plan. Thereafter during the Minimum Commercial Performance Period, the Minimum Commercial Performance will be updated [*], to reflect any changes in the timing of Regulatory Approvals and the First Commercial Sale of a Product for each approved indication in the Collaborator Territory as well as actual experience and competitive conditions then prevailing.

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

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

January 1st following the date of the First Commercial Sale of the Product in the Collaborator Territory and ending on December 31st of such Calendar Year. For example, if the First Commercial Sale of the Product occurs in August 2021, the First Full Calendar Year begins on January 1, 2022 and ends on December 31, 2022.

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

6.4 Coordination of Commercialization Activities.

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

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

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

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

6.5 Detailing and Promotion.

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

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

6.6 Medical Affairs Activities.

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

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

6.7 Diversion. Each Party hereby covenants and agrees that it and its Affiliates shall not, and it shall contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its sublicensees not to, directly or indirectly, promote, market, distribute, import, sell, or have sold any Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory. Neither Party shall engage, nor permit its Affiliates and sublicensees to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of such Product located in any country or jurisdiction in the other Party's

territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or sublicensees receives any order for a Product for use from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates and sublicensees to, deliver or tender (or cause to be delivered or tendered) any Product for use in the other Party's territory.

7. Manufacture and Supply.

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

8. Financial Provisions

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

8.2 Sharing/Reimbursements of Development Costs and PV Costs.

(a) Future Development Costs. No later than [*] after the beginning of each Calendar Quarter during which a Party will perform any Collaborative Work in such Calendar Quarter pursuant to the GDP, such Party shall submit to the other Party a statement setting forth the Development Costs incurred, including the other Party's share (calculated in accordance with Section 4.5) of (i) estimated Development Costs for the then current quarter; (ii)

variances from prior invoiced estimates and actual Development Costs; and (iii) Development Costs incurred by or on account of such Party in the past quarter not previously invoiced. Such invoice shall include a reasonably detailed report for such Development Costs, including supporting documents. To the extent provided in Section 4.5, the other Party shall pay the amount invoiced within [*] after the receipt of the invoice. For clarity, making such a payment does not preempt the paying Party's audit rights under Section 9.4, which remain in full force and effect. If both Parties will perform Development activities under the GDP in such Calendar Quarter, the Parties shall consolidate the payments for such Calendar Quarter into a single payment from one Party to the other Party.

(b) Independent Work. Subject to Section 4.7(b), and except as set forth below in this Section 8.2(b), each Party shall bear all the internal (calculated on an FTE basis using the then current FTE Rate) and reasonable out-of-pocket expenses incurred by or on account of such Party in performing its own Independent Work (the "**Independent Work Costs**"). After the completion of such Independent Work, such Party shall provide the other Party with a report of such Independent Work Costs. If a Party desires to submit any portion of the Data resulting from any Independent Work conducted by the other Party and related Regulatory Filings generated by the other Party to support Regulatory Approval in its territory, then such Party shall notify the other Party in writing at any time upon the completion of such Independent Work. Within [*] after its receipt of such notice, the Party conducting or having conducted such Independent Work shall submit to the other Party a reasonably detailed invoice setting forth [*] of the Independent Work Costs that would have been incurred by or on account of such other Party in connection with the generation of such Data under Section 8.2(b) as if such Independent Work Costs were Development Costs with respect to Collaborative Work. If the Party seeking to use such Data decides to use such Data to support Regulatory Approval in its territory, then such Party shall notify the other Party in writing and pay the amount invoiced (i.e., if Collaborator seeks to use the Data resulting from Exelixis' Independent Work, twenty percent (20%) of [*] of the Independent Work Costs) within [*] after the receipt of such invoice. For clarity, making such a payment does not preempt the paying Party's audit rights under Section 9.4, which remain in full force and effect.

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

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

(e) PV Costs Following Initiation of Clinical Trials. Following the Initiation of the first Clinical Trial in the Collaborator Territory, no later than [*] after the beginning of each Calendar Quarter, Exelixis shall submit to Collaborator a statement setting forth the PV Costs incurred, including Collaborator's share (calculated in accordance with

Section 5.5) of (i) estimated PV Costs for the then current quarter; (ii) variances from prior invoiced estimates and actual PV Costs; and (iii) PV Costs incurred by or on account of Exelixis in the past quarter not previously invoiced. Such invoice shall include a reasonably detailed report for such PV Costs, including supporting documents. To the extent provided in Section 5.5, Collaborator shall pay the amount invoiced within [*] after the receipt of the invoice. For clarity, making such a payment does not preempt Collaborator's audit rights under Section 9.4, which remain in full force and effect.

8.3 Development Milestone Payments.

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

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

[*] = 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.

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

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

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

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

8.4 Sales-Based Milestones Payments.

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

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

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

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

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

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

8.5 Royalty Payments.

(a) Royalty Rate. Subject to the other terms of this Section 8.5, during the Royalty Term, Collaborator shall make quarterly, non-refundable, non-creditable royalty payments to Exelixis on the annual Net Sales of all Products sold in the Collaborator Territory at the applicable rate set forth in the table below. For clarity, if the threshold in Section 8.5(b) is

achieved in any Calendar Year, then the Net Sales for purposes of this Section 8.5(a) will commence on the date after which such threshold is achieved.

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

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

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

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

(d) Royalty Rate Adjustment for Collaborator Patents. If the Royalty Term extends beyond the expiration of the last-to-expire Valid Claim of the [*] Patents, and any Regulatory Exclusivity [*] (the "**Remaining Royalty Term**"), the royalty rates to be paid by Collaborator to Exelixis during the Remaining Royalty Term shall be reduced by [*] of the amounts otherwise applicable under Section 8.5(a).

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

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

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

9. Payment; Records; Audits

9.1 Payment; Reports. Royalty payments due by Collaborator to Exelixis under Section 8.5 shall be calculated and reported for each Calendar Quarter during the Royalty Term. Within [*] after the end of each month during the Royalty Term, Collaborator shall provide to Exelixis a preliminary report setting forth the gross amount of sales of the Products by Collaborator and its Affiliates and Sublicensees in the Collaborator Territory during such month. Within [*] after the end of each Calendar Quarter during the Royalty Term, Collaborator shall provide to Exelixis a preliminary report setting forth the estimated Net Sales of the Products by Collaborator and its Affiliates and Sublicensees in the Collaborator Territory during such Calendar Quarter. Within [*] after the end of each Calendar Quarter, Collaborator shall deliver to Exelixis all royalty payments due under Section 8.5. Each such payment shall be accompanied by a final report setting forth the Net Sales of the Products by Collaborator and its

Affiliates and Sublicensees in the Collaborator Territory in such Calendar Quarter in sufficient detail to permit confirmation of the accuracy of the royalty payment made, including the number of Products sold, the gross sales and Net Sales of Products, including the deductions from gross sales to arrive at Net Sales, the royalties payable, the method used to calculate the royalties, the exchange rates used, and whether any commercial milestone under Section 8.4 has been achieved. Collaborator shall submit a single report for all Net Sales during the Calendar Quarter, including all of Collaborator's and its Affiliates' and Sublicensees' Net Sales, but shall separately identify the Net Sales and other information applicable to each entity.

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

9.3 Taxes.

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

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

(c) Taxes Resulting From Collaborator's Action. Collaborator represents and warrants that, as of the Effective Date, (i) Collaborator is not required by Applicable Law to deduct or withhold taxes on the upfront payment, milestone payments, royalty payments, and other payments payable to Exelixis under this Agreement and (ii) no transfer taxes will be

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

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

9.5 Late Payments. In the event that any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due at [*]; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the

Party entitled to receive payment from exercising any other rights it may have as a consequence of the lateness of any payment.

10. Intellectual Property

10.1 Ownership.

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

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

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

(ii) Except for Compound Inventions, each Party shall solely own any Inventions made solely by its and its Affiliates' employees, agents, or independent contractors (the "**Sole Inventions**"), and the Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of one Party or its Affiliates together with employees, agents, or independent contractors of the other Party or its Affiliates (the "**Joint Inventions**"). All Patents claiming patentable Joint Inventions shall be referred to herein as "**Joint Patents.**" Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license, assign, and

otherwise exploit its interest under the Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party.

10.2 Patent Prosecution and Maintenance.

(a) Exelixis Patents.

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

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

(b) Collaborator Patents.

(i) Subject to this Section 10.2(b), Collaborator shall have the first right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings and

defense of validity or enforceability challenges) of all Collaborator Patents (other than Joint Patents) worldwide, at its sole cost and expense and by counsel of its own choice in the Collaborator Territory and by counsel mutually agreed to by the Parties in the Exelixis Territory. Collaborator shall keep Exelixis informed of the status of filing, prosecution, maintenance and defense, if any, of the Collaborator Patents, and Collaborator shall consult with, and consider in good faith the requests and suggestions of, Exelixis with respect to strategies for filing, prosecuting and defending, if any, Collaborator Patents.

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

(c) Joint Patents.

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

(ii) In the event that Exelixis desires to abandon or cease prosecution or maintenance of any Joint Patent in the Collaborator Territory, Exelixis shall provide reasonable prior written notice to Collaborator of such intention to abandon (which notice shall,

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

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

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

10.4 Patent Enforcement.

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

similar action alleging the invalidity, unenforceability, or non-infringement of any of the Exelixis Patents (collectively "**Product Infringement**").

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

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

(d) Expense and Recovery.

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

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

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

Patents, including the defense of validity and enforceability challenges arising from any enforcement action.

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

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

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

10.8 Trademarks.

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

requests and suggestions of, Collaborator with respect to strategies for filing, prosecuting, and defending, if any, the Product Marks in the Collaborator Territory.

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

11. Representations and Warranties

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

11.2 Covenants.

(a) Employees, Consultants, and Contractors. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants, and contractors who perform Development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign (or, in the case of contractor, grant a license under) Inventions in a manner consistent with the provisions of this Agreement.

(b) Debarment. Each Party represents, warrants, and covenants to the other Party that it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to any Product. In the event that either

Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, including the Party itself or its Affiliates or Sublicensees, that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

(c) **Compliance**. Each Party covenants as follows:

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

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

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

(iv) Each Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any other Applicable Laws in connection with the performance of this Agreement or the Development, manufacture, or Commercialization of any Product.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11.5 Disclaimer. Except as expressly set forth in this Agreement, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. Without limiting the foregoing, (a) neither Party represents or warrants that any data obtained from conducting Clinical Trials in one country or jurisdiction will comply with the laws and regulations of any other country or jurisdiction, and (b) neither Party represents or warrants the success of any study or test conducted by it pursuant to this Agreement, or the safety or usefulness for any purpose of the technology it provides hereunder.

12. Indemnification

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

12.2 Indemnification by Collaborator. Collaborator hereby agrees to defend, indemnify, and hold harmless Exelixis, its Affiliates, and licensees and their respective directors, officers, employees, and agents (each, an "**Exelixis Indemnitee**") from and against any and all Losses to which any Exelixis Indemnitee may become subject as a result of any claim, demand,

action, or other proceeding by any Third Party to the extent such Losses arise out of: (a) the manufacturing, Development, use, handling, storage, Commercialization, or other disposition of any Compound or Product by Collaborator, its Affiliates, or Sublicensees or the contractor of any of them, (b) the negligence or willful misconduct of any Collaborator Indemnitee, or (c) the breach by Collaborator of any warranty, representation, covenant, or agreement made by Collaborator in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of any activities set forth in Sections 12.1(a)-(c) for which Exelixis is obligated to indemnify the Collaborator Indemnitee under Section 12.1.

12.3 Procedure. A party that intends to claim indemnification under this Article 12 (the "**Indemnitee**") shall promptly notify the indemnifying Party (the "**Indemnitor**") in writing of any Third Party claim, demand, action, or other proceeding (each, a "**Claim**") in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof. The Indemnitee may participate, at its expense and using its own counsel, in the Indemnitor's defense of and settlement negotiations for any Claim. The indemnity arrangement in this Article 12 shall not apply to amounts paid in settlement of any action with respect to a Claim if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 12 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

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

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

13. Confidentiality

13.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that, during the Term and for [*] thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose, and shall not use for any purpose other than as expressly provided for in this Agreement, any Confidential Information of the other Party, and both Parties shall keep confidential and, subject to Sections 13.2 and 13.3 and 13.4, shall not publish or otherwise

[*] = 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.

disclose the terms of this Agreement. Each Party may use the other Party's Confidential Information only to the extent required to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations under this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own of similar nature (but no less than reasonable care) to ensure that its officers, directors, employees, agents, consultants, contractors, and other representatives do not disclose or make any unauthorized use of the Confidential Information of the other Party. Each Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information of the other Party.

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

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

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

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

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

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

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

(f) disclosure to its and its Affiliates' officers, directors, employees, consultants, contractors, and agents, to its licensees and sublicensees, in each case on a need-to-know basis in connection with the Development, manufacture, or Commercialization of the Compound and Products in accordance with the terms of this Agreement, in each case under written obligations of confidentiality and non-use at least as stringent as those herein. For the

avoidance of any doubt, Collaborator shall not be permitted to disclose, for any reason, any Confidential Information of Exelixis to [*] or [*] without Exelixis' prior written consent.

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

13.4 Publications.

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

(b) If the Responding Party believes that the subject matter of the proposed publication or other disclosure contains Confidential Information or a patentable invention of the Responding Party, then prior to the expiration of the applicable time period for review, the Responding Party shall notify the Submitting Party in writing of its determination that such proposed publication or other disclosure, as applicable, contains such information or subject matter for which patent protection should be sought. Upon receipt of such written notice from the Responding Party, the Submitting Party shall delay public disclosure of such information or submission of the proposed publication for an additional period of [*] (or such other time period mutually agreed by the Parties in writing) to permit preparation and filing of a patent application on the disclosed subject matter. The Submitting Party shall thereafter provide the Responding Party with a copy of final version of publication materials and be free to publish or disclose such information, except that the Submitting Party may not disclose any Confidential Information of the Responding Party in violation of Section 13.1.

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

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

14. Term and Termination

14.1 Term.

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

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

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

[*] = 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.

14.2 Termination for Cause.

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

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

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

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

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

14.3 Termination without Cause.

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

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

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

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

(b) Regulatory Materials; Data. Within [*] of the effective date of termination of this Agreement, Collaborator shall transfer and assign to Exelixis, at no cost to Exelixis, all Regulatory Filings and Regulatory Approvals for the Products, Data from all preclinical, non-clinical and clinical studies conducted by or on behalf of Collaborator, its Affiliates, or Sublicensees on the Products, and all pharmacovigilance data (including any adverse events database) on the Products. In the event any Regulatory Filings and/or Regulatory Approval for a Product cannot be transferred to Exelixis within such [*] period, Collaborator shall continue to maintain such Regulatory Fillings and/or Regulatory Approval until such time as Collaborator is permitted to transfer such Regulatory Filing or Regulatory Approval to

Exelixis. In addition, at Exelixis' request, Collaborator shall provide Exelixis with reasonable assistance with any inquiries and correspondence with Regulatory Filings and Regulatory Authorities regarding the Product in the Collaborator Territory for a period of [*] after such termination. Exelixis shall be responsible for Collaborator's reasonable costs incurred directly in connection with any such Exelixis request.

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

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

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

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

the continuation of such services for Exelixis from such entity, or Collaborator shall continue to perform such work for Exelixis, as applicable, for a reasonable period (not to exceed [*]) after termination at Exelixis' cost until Exelixis establishes an alternate, validated source of such services.

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

(h) Non-Compete. Following any termination of this Agreement by Collaborator pursuant to Section 14.3(b), or by Exelixis pursuant to Section 14.2, neither Collaborator nor any of its Affiliates shall (directly or indirectly, either with or without a bona fide Collaborator or any other Third Party) (i) develop any Competing Product in the Collaborator Territory for a period of [*] following the effective date of such termination, or (ii) commercialize any Competing Product in the Collaborator Territory for a period of [*] following the effective date of such termination.

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

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

14.6 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and otherwise will be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties agree that a Party that is a licensee of such rights under this Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party to this Agreement under the U.S. Bankruptcy Code or comparable provision of

applicable bankruptcy or insolvency laws, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party.

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

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

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

15. Dispute Resolution

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

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

15.3 Dispute Resolution.

(a) If the Parties are unable to resolve a Disputed Matter using the process described in Section 15.2, then a Party seeking further resolution of the Disputed Matter will submit the Disputed Matter to resolution by final and binding arbitration. Whenever a Party will decide to institute arbitration proceedings, it will give written notice to that effect to the other Party. Arbitration will be held in [*], and administered by the International Chamber of Commerce pursuant to its ICC International Arbitration Rules then in effect (the "**Rules**"), except as otherwise provided herein and applying the substantive law specified in Section 16.1. The arbitration will be conducted by a panel of three (3) arbitrators appointed in accordance with the Rules; provided that each Party will, within [*] after the institution of the arbitration proceedings, appoint an arbitrator, and such arbitrators will together, within [*], select a third (3rd) arbitrator as the chairman of the arbitration panel. Each arbitrator must have significant business or legal experience in the pharmaceutical business. If the two (2) initial arbitrators are unable to select a third (3rd) arbitrator within such [*] period, the third (3rd) arbitrator will be appointed in accordance with Rules. In addition to the authority conferred by the Rules, the Parties hereby agree to engage in discovery of information and evidence that is or might be relevant to the claims, defenses, and issues in the dispute, including by means of discovery in the form of [*], subject to [*] being permitted by the panel of arbitrators on a showing of good cause. The Parties further agree to the ability, right, and power to subpoena Third Party witnesses for both discovery and hearing purposes. After conducting any hearing and taking any evidence deemed appropriate for consideration, the arbitrators will render their opinion within [*] of the final arbitration hearing. The panel of arbitrators will not have the power to award damages excluded pursuant to Section 12.5 under this Agreement and any arbitral award that purports to award such damages is expressly prohibited and void ab initio. Decisions of the panel of arbitrators that conform to the terms of this Section 15.3 will be final and binding on the Parties and judgment on the award so rendered may be entered in any court of competent jurisdiction. The losing Party, as determined by the panel of arbitrators, will pay all of the ICC administrative costs and fees of the arbitration and the fees and costs of the arbitrators, and the arbitrators will be directed to provide for payment or reimbursement of such fees and costs by the losing Party. If the panel of arbitrators determines that there is no losing Party, the Parties will each be responsible for one-half of those costs and fees and the arbitrators' award will so provide. Notwithstanding the foregoing, each Party shall be responsible for its own attorneys' fees, expert or witness fees, and any other fees and costs, and no such fees or costs will be shifted to the other Party.

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

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

16. General Provisions

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

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

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

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

forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition.

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

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

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

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

16.6 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. The Parties will in such an instance use their best efforts to replace the invalid, unenforceable, or illegal provision(s) with valid, enforceable, and legal provision(s) that implement the purposes of this Agreement.

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

If to Collaborator, notices must be addressed to:

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

with a copy to:

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

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

If to Exelixis, notices must be addressed to:

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

16.8 Standstill.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16.10 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections, and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words "herein", "hereof", and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All

references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language.

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

{Signature Page Follows}

In Witness Whereof, the Parties hereto have caused this **Collaboration and License Agreement** to be executed and entered into by their duly authorized representatives as of the Effective Date.

Exelixis, Inc.	**Takeda Pharmaceutical Company Limited**
By: /s/ Michael M. Morrissey	By: /s/ Tsudoi Miyoshi
Name: Michael M. Morrissey, Ph.D.	Name: Tsudoi Miyoshi
Title: President and Chief Executive Officer	Title: Head of Japan Oncology Business Unit

[*] = 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 1.2: Chemical Structure of cabozantinib

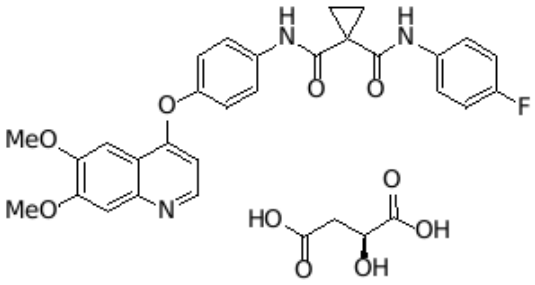
Exhibit 1.31: Exelixis Patents

Exhibit 4.2: Initial Global Development Plan and Budget

Exhibit 13.5: Press Release

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

Exhibit 1.2
Chemical Structure of cabozantinib



Cabozantinib (*S*)-malate salt

[*] = 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 1.31
Exelixis Patents

{Redacted content comprises approximately 4 pages}
[*]

[*] = 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 4.2
Initial Global Development Plan and Budget

{Redacted content comprises approximately 6 pages}

[*]

[*] = 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 13.5
Press Release

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

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

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

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

"As an organization with a strong focus on oncology innovation, our agreement with Exelixis brings a promising and well-studied solid-tumor therapy to our pipeline that may help patients in Japan suffering from RCC and potentially other equally devastating cancers," said Tsudoi Miyoshi, Head of Japan Oncology Business Unit of Takeda. "We intend to pursue regulatory approval for RCC indications as soon as we're able, and look forward to commencing the local clinical trial program to further strengthen the clinical profile of cabozantinib."
Exelixis and Takeda will partner on cabozantinib's clinical development in Japan and on translating existing and forthcoming clinical data for potential regulatory filings in the country. In the METEOR pivotal trial, cabozantinib demonstrated statistically significant improvements in overall survival, progression-free survival and objective response rate, meaningfully differentiating it from other therapies to treat advanced renal cell carcinoma following prior therapy. In addition to advanced RCC, future indications could include advanced hepatocellular cancer (HCC), the subject of the CELESTIAL global pivotal trial for which results are anticipated in 2017. Additional earlier-stage studies are under way through Exelixis' collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program, and its ongoing Investigator-Sponsored Trial program. Through these two programs, there are more than 45 ongoing or planned studies including trials in advanced RCC, bladder cancer, colorectal cancer, non-small cell lung cancer, and endometrial cancer.

"Takeda is the ideal partner to advance cabozantinib in Japan and deliver this important treatment option to Japanese patients with cancer," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Takeda is widely respected for both its clinical development and commercial expertise. We look forward to supporting our new partner as it pursues Japanese regulatory approval for cabozantinib, while simultaneously working together to plan the next steps for clinical development in the country. This agreement further propels the global progress for cabozantinib development and commercialization, which now includes the recent first commercial sale of CABOMETYX in the United Kingdom, triggering a $10 million milestone payment from Ipsen to Exelixis."

[*] = 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.

Cabozantinib is not approved for use in Japan. Previously, Exelixis and its collaborators conducted early-stage clinical trials in Japan, including a phase 1 trial in advanced solid tumors. Data from this trial were presented at the European Society for Medical Oncology 2012 Congress and the 2015 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.[1,2]

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

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

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

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

U.S. Important Safety Information

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

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

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

Hypertension and Hypertensive Crisis: CABOMETYX treatment results in an increased incidence of treatment-emergent hypertension. Hypertension was reported in 37% (15% Grade ≥3) of CABOMETYX-treated patients and 7.1% (3.1% Grade ≥3) of everolimus-treated patients. Monitor blood pressure prior to

[1] Nokihara et al., Molecular profile and anti-tumor activity in non-small cell lung cancer (NSCLC) patients (pts) in a phase 1 study of cabozantinib (XL184) in Japan. *Ann Oncol.* 2012; 23 (suppl 9): ix152-ix174.
[2] Nokihara et al., Final results of a phase 1 study of cabozantinib (Cabo) in Japanese patients (pts) with expansion cohorts in non-small cell lung cancer (NSCLC) with defined molecular alterations. *Mol Cancer Ther.* December 1 2015 (14) (12 Supplement 2) B179.

initiation and regularly during CABOMETYX treatment. Withhold CABOMETYX for hypertension that is not adequately controlled with medical management; when controlled, resume CABOMETYX at a reduced dose. Discontinue CABOMETYX for severe hypertension that cannot be controlled with anti-hypertensive therapy. Discontinue CABOMETYX if there is evidence of hypertensive crisis or severe hypertension despite optimal medical management.

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

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

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

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

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

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

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

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

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

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

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

[*] = 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.

are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit http://www.takeda.com/news.

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

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

Exelixis Forward-Looking Statements
This press release contains forward-looking statements, including, without limitation, statements related to: the future clinical development of cabozantinib by Exelixis and Takeda in Japan; Exelixis' receipt of a $50 million upfront payment; Exelixis' eligibility to receive development, regulatory and first-sales milestones of $95 million for the first three planned indications; Exelixis' eligibility to receive royalties on sales of cabozantinib by Takeda; the clinical and therapeutic potential of cabozantinib for patients in Japan suffering from RCC and potentially other cancers; Takeda's intent to pursue regulatory approval for cabozantinib in RCC indications and commence a local clinical trial program; Exelixis' and Takeda's plan to translate existing and forthcoming clinical data for potential regulatory filings in Japan; advanced HCC as a potential future commercial indication; the timing of anticipated results from CELESTIAL; the continued development of cabozantinib through Exelixis' collaboration with the National Cancer Institute's Cancer Therapy Evaluation Program, and its ongoing Investigator-Sponsored Trial program; Exelixis' intent to support Takeda as it pursues Japanese regulatory approval for cabozantinib, while simultaneously working together to plan the next steps for clinical development in Japan; Exelixis' commitment to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer; Exelixis' focus on advancing cabozantinib; and the continued development of cobimetinib. Words such as "potential," "further," "will," "eligible," "planned," "may," "intend," "look forward," "future," "could," "anticipated," "next," "committed," "focused," or other similar expressions identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the complexities and challenges associated with regulatory review and approval processes; Exelixis' dependence on its relationship with Takeda, including, the level of Takeda's investment in the resources necessary to successfully commercialize cabozantinib in Japan; the degree of market acceptance of CABOMETYX and the availability of coverage and reimbursement for CABOMETYX; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; Exelixis' dependence on its relationship with other collaborators, including Ipsen with respect to cabozantinib in territories outside of the United States and Japan and Genentech/Roche with respect to cobimetinib; Exelixis' dependence on third-party vendors; Exelixis' ability to protect the company's intellectual property rights; market competition; changes in economic and business conditions, and other factors discussed under the caption "Risk Factors" in Exelixis' quarterly report on

[*] = 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.

Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 3, 2016, and in Exelixis' future filings with the SEC. The forward-looking statements made in this press release speak only as of the date of this press release. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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Exhibit 10.2

SECOND AMENDMENT TO COLLABORATION AND LICENSE AGREEMENT

This **Second Amendment to the Collaboration and License Agreement** (the "**Amendment**") is entered into as of May 7, 2019 (the "**Amendment Effective Date**") by and between Exelixis, Inc., a Delaware company having an address at 1851 Harbor Bay Parkway, Alameda, CA, 94502, USA ("**Exelixis**") and Takeda Pharmaceutical Company Limited, a Japanese corporation with principal offices located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, JAPAN ("**Collaborator**"). Exelixis and Collaborator may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

Recitals

Whereas, Exelixis and Collaborator are parties to the Collaboration and License Agreement dated January 30, 2017, as amended on March 22, 2018 (the "**License Agreement**"), under which the Parties have been collaborating on the development and commercialization of cabozantinib in Japan; and

Whereas, the Parties desire to enter into this Amendment to modify certain reimbursement obligations and certain milestone payments payable under the License Agreement 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. Regulatory Activities

1.1 Section 5.5(c) of the License Agreement is hereby deleted in its entirety and replaced with the following:

(c) PV Costs. As between the Parties, Exelixis shall be responsible for the cost and expense incurred by Exelixis for establishing and maintaining such global safety database and the preparation of periodic aggregate safety reports that are specifically directed (or reasonably allocable) to the Product (the "**PV Costs**") prior to [*]. For the period of time commencing upon [*] until [*], Exelixis shall be responsible for [*] of PV Costs and Collaborator shall be responsible for [*] of PV Costs. Thereafter, Exelixis shall be responsible for [*] of PV Costs and Collaborator shall be responsible for [*] of PV Costs; provided, however, that in no event shall Collaborator be responsible for more than one million U.S. dollars ($1,000,000) in PV Costs in any Calendar Year during such period of time.

2. Financial Provisions

2.1 Development Milestone Payments. The milestone table in Section 8.3(a) of the License Agreement is hereby deleted in its entirety and replaced with the following:

Milestone Event	**Milestone Payments**							
	For HCC (2nd line)	For RCC (2nd line)	For RCC (1st line) as a combination therapy (including, for clarity, the Takeda 9ER Trial Opt-In)	For RCC (1st line) as a single agent	Tier 1 Indications	Tier 2 Indications	Tier 3 Indications: Clinical Trial sponsored by Collaborator or its Affiliate	Tier 3 Indications: Investigator-Initiated Clinical Trial
Milestone #1: Upon [*] the first Phase 3 Clinical Trial for the Product in Collaborator Territory	[*]	[*]	$[*]	[*]	$[*]	$[*]	$[*]	[*]
Milestone #2: Upon filing the first MAA for the Product in Collaborator Territory	$10 million	$16 million	$10 million	[*]	$[*]	$[*]	[*]	$[*]
Milestone #3: Upon First Commercial Sale for the Product in the relevant indication in Collaborator Territory	$15 million	$[*]	$20 million	$[*]	$[*]	$[*]	[*]	[*]

[*] = 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.

2.2 Cumulative Net Sales Milestones. The milestone table in Section 8.4(c) of the License Agreement is hereby deleted in its entirety and replaced with the following:

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

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 Amendment Effective Date, shall remain in full force and effect.

3.2 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.

3.3 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.

3.4 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 **Second Amendment** to be executed and entered into by their duly authorized representatives as of the Amendment Effective Date.

Exelixis, Inc.

By: /s/ Michael M. Morrissey, Ph.D.

Name: Michael M. Morrissey, Ph.D.

Title: President and Chief Executive Officer

Takeda Pharmaceutical Company Limited

By: /s/ Tsudoi Miyoshi

Name: Tsudoi Miyoshi

Title: Head of Japan Oncology Business Unit

[*] = 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 10, 2022

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 10, 2022

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 1, 2022, 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 10th day of May 2022.

/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)