Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

OR

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

Commission file number 001-37359

BLUEPRINT MEDICINES CORPORATION
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**26-3632015**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
45 Sidney Street Cambridge, Massachusetts	**02139**
(Address of Principal Executive Offices)	**(Zip Code)**

(617) 374-7580
(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 (§232.405 of this chapter) 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, smaller reporting company, or an emerging growth company. See 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 Exchange Act. ☐

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

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, par value $0.001 per share	BPMC	Nasdaq Global Select Market

Number of shares of the registrant's common stock, $0.001 par value, outstanding on April 29, 2022: 59,570,547

TABLE OF CONTENTS

Unless otherwise stated, all references to "us," "our," "Blueprint," "Blueprint Medicines," "we," the "Company" and similar designations in this Quarterly Report on Form 10-Q refer to Blueprint Medicines Corporation and its consolidated subsidiaries. Blueprint Medicines, AYVAKIT®, AYVAKYT®, GAVRETO® and associated logos are trademarks of Blueprint Medicines Corporation. Other brands, names and trademarks contained in this Quarterly Report on Form 10-Q are the property of their respective owners.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would" or the negative of these words or other comparable terminology, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the timing or likelihood of regulatory actions, filings and approvals for our current and future drug candidates, including our ability to obtain marketing approval for avapritinib and pralsetinib for additional indications or in additional geographies;
- our ability and plans in continuing to expand out our commercial infrastructure and successfully launching, marketing and selling AYVAKIT® (avapritinib) (marketed in Europe under the brand name AYVAKYT®), GAVRETO® (pralsetinib) and any current and future drug candidates for which we receive marketing approval;
- the rate and degree of market acceptance of AYVAKIT/AYVAKYT, GAVRETO and any current and future drug candidates for which we receive marketing approval;
- the pricing and reimbursement of AYVAKIT/AYVAKYT, GAVRETO and any current and future drug candidates for which we receive marketing approval;
- the initiation, timing, progress and results of our preclinical studies and clinical trials, including our ongoing clinical trials and any planned clinical trials for our current and future drug candidates as monotherapies or in combination with other agents and research and development programs;
- our ability to advance drug candidates into, and successfully complete, clinical trials;
- our ability to successfully develop manufacturing processes for any of our current and future drugs or drug candidates and to secure manufacturing, packaging and labeling arrangements for development activities and commercial production;
- the implementation of our business model and strategic plans for our business, drugs, drug candidates, platform and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our current and future drugs, drug candidates and technology;
- the potential benefits of our collaboration with F. Hoffmann-La Roche Ltd and Genentech, Inc. to develop and commercialize pralsetinib globally (excluding Greater China), our cancer immunotherapy collaboration with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., our collaboration with CStone Pharmaceuticals to develop and commercialize avapritinib, pralsetinib and fisogatinib in Greater China, our collaboration with Zai Lab to develop and commercialize BLU-701 and BLU-945 as inhibitors of epidermal growth factor receptor (EGFR), and our collaboration with Proteovant Therapeutics to discover and advance novel targeted protein degrader therapies, as well as our ability to maintain these collaborations and establish additional strategic collaborations;

- the potential benefits of our exclusive license agreement with Clementia Pharmaceuticals, Inc. to develop and commercialize BLU-782 for fibrodysplasia ossificans progressiva;
- the development of companion diagnostic tests for our current or future drugs or drug candidates;
- our financial performance, estimates of our revenues, expenses and capital requirements and our needs for future financing, including our ability to achieve a self-sustainable financial profile;
- developments relating to our competitors and our industry;
- the actual or potential benefits of designations granted by the U.S. Food and Drug Administration (FDA), such as orphan drug, fast track and breakthrough therapy designation or priority review; and
- the impact and scope of the ongoing COVID-19 pandemic on our business, operations, strategy, goals and anticipated milestones, including our ongoing and planned research and discovery activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, and the launch, marketing, sale and commercial supply of AYVAKIT/AYVAKYT, GAVRETO and any current or future drug candidates for which we receive marketing approval.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results, performance or achievements may be materially different from what we expect. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

For purposes of this Quarterly Report on Form 10-Q, including the footnotes to our condensed consolidated financial statements, (i) with respect to our collaboration for pralsetinib, Roche means F. Hoffmann-La Roche Ltd and Genentech, Inc., and (ii) with respect to our cancer immunotherapy collaboration, Roche means F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Blueprint Medicines Corporation
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 37,199	$ 209,948
Marketable securities	549,627	267,166
Accounts receivable	28,758	25,155
Unbilled accounts receivable	3,840	11,875
Inventory	30,145	21,817
Prepaid expenses and other current assets	37,675	18,064
Total current assets	687,244	554,025
Marketable securities	306,525	557,529
Property and equipment, net	31,110	30,700
Operating lease right-of-use assets, net	88,119	90,162
Restricted cash	5,171	5,171
Other assets	25,138	14,638
Total assets	$ 1,143,307	$ 1,252,225
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	17,961	8,333
Accrued expenses	100,698	121,829
Current portion of operating lease liabilities	8,762	8,093
Current portion of deferred revenue	9,604	11,510
Total current liabilities	137,025	149,765
Operating lease liabilities, net of current portion	100,762	103,315
Deferred revenue, net of current portion	13,721	25,066
Other long-term liabilities	10,133	3,344
Total liabilities	261,641	281,490
Commitments and Contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 120,000,000 shares authorized; 59,555,974 and 59,141,086 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	60	59
Additional paid-in capital	2,275,156	2,250,250
Accumulated other comprehensive loss	(12,110)	(4,133)
Accumulated deficit	(1,381,440)	(1,275,441)
Total stockholders' equity	881,666	970,735
Total liabilities and stockholders' equity	$ 1,143,307	$ 1,252,225

Blueprint Medicines Corporation
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Revenues:		
Product revenue, net	$ 23,841	$ 8,955
Collaboration revenue	38,890	12,621
Total revenues	62,731	21,576
Cost and operating expenses:		
Cost of sales	5,079	102
Collaboration loss sharing	3,265	—
Research and development	103,133	79,710
Selling, general and administrative	57,058	42,002
Total cost and operating expenses	168,535	121,814
Other income (expense):		
Interest income, net	442	738
Other expense, net	(453)	(214)
Total other income (expense)	(11)	524
Loss before income taxes	(105,815)	(99,714)
Income tax expense	184	—
Net loss	$ (105,999)	$ (99,714)
Other comprehensive income (loss):		
Unrealized losses on available-for-sale investments	(8,020)	(400)
Currency translation adjustments	43	517
Comprehensive loss	$ (113,976)	$ (99,597)
Net loss per share - basic and diluted	$ (1.79)	$ (1.72)
Weighted-average number of common shares used in net loss per share - basic and diluted	59,312	58,023

Blueprint Medicines Corporation
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	59,141,086	$ 59	$ 2,250,250	$ (4,133)	$ (1,275,441)	$ 970,735
Issuance of common stock under stock plan	414,888	1	1,297	—	—	1,298
Stock-based compensation expense	—	—	23,609	—	—	23,609
Other comprehensive income	—	—	—	(7,977)	—	(7,977)
Net loss	—	—	—	—	(105,999)	(105,999)
Balance at March 31, 2022	59,555,974	$ 60	$ 2,275,156	$ (12,110)	$ (1,381,440)	$ 881,666
Balance at December 31, 2020	57,793,533	$ 58	$ 2,106,600	$ (5,214)	$ (631,356)	$ 1,470,088
Issuance of common stock under stock plan	483,879	—	8,318	—	—	8,318
Stock-based compensation expense	—	—	21,212	—	—	21,212
Other comprehensive income	—	—	—	117	—	117
Net loss	—	—	—	—	(99,714)	(99,714)
Balance at March 31, 2021	58,277,412	$ 58	$ 2,136,130	$ (5,097)	$ (731,070)	$ 1,400,021

Blueprint Medicines Corporation
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (105,999)	$ (99,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,628	1,608
Noncash lease expense	2,037	1,522
Stock-based compensation	23,399	20,684
Other	813	536
Changes in assets and liabilities:		
Accounts receivable	(3,645)	(27,613)
Unbilled accounts receivable	8,035	9,013
Inventory	(9,828)	(4,837)
Prepaid expenses and other current assets	(19,588)	(2,594)
Other assets	(13,741)	(44)
Accounts payable	9,516	(1,464)
Accrued expenses	(17,049)	(21,312)
Other long-term liabilities	6,826	527
Deferred revenue	(13,251)	(185)
Operating lease liabilities	(1,879)	(1,905)
Net cash provided used in operating activities	(132,726)	(125,778)
Cash flows from investing activities		
Purchases of property and equipment	(1,153)	(173)
Purchases of investments	(39,937)	(83,080)
Maturities of investments	—	215,450
Net cash provided by (used in) investing activities	(41,090)	132,197
Cash flows from financing activities		
Net proceeds from stock option exercises and employee stock purchase plan	1,264	7,011
Net cash provided by financing activities	1,264	7,011
Net increase (decrease) in cash, cash equivalents, and restricted cash	(172,552)	13,430
Cash, cash equivalents and restricted cash at beginning of period	215,119	689,804
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(197)	(97)
Cash, cash equivalents and restricted cash at end of period	$ 42,370	$ 703,137
Supplemental cash flow information		
Property and equipment purchases unpaid at period end	$ 1,036	$ 443
Cash paid for taxes, net	$ 169	$ 574

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows (in thousands).

	March 31, 2022	**March 31, 2021**
Cash and cash equivalents	$ 37,199	$ 697,966
Restricted cash	5,171	5,171
Total cash, cash equivalents, and restricted cash shown in condensed consolidated statements of cash flows	$ 42,370	$ 703,137

Blueprint Medicines Corporation
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Nature of Business

Blueprint Medicines Corporation (the Company), a Delaware corporation incorporated on October 14, 2008, is a precision therapy company focused on genomically defined cancers and blood disorders. The Company's approach is to leverage its novel research engine to systematically and reproducibly identify drivers of diseases in genomically defined patient populations, and to craft highly selective and potent drug candidates that are intended to provide significant and durable clinical responses to patients.

The Company has two approved precision therapies and is globally advancing multiple programs for systemic mastocytosis, lung cancer and other genomically defined cancers, and cancer immunotherapy. The Company is devoting substantially all of its efforts to research and development for current and future drug candidates and commercialization of AYVAKIT/AYVAKYT, GAVRETO and any current or future drug candidates that obtain marketing approval.

As of March 31, 2022, the Company had cash, cash equivalents and marketable securities of $893.4 million. Based on the Company's current operating plans, the Company anticipates that its existing cash, cash equivalents and marketable securities will be sufficient to enable it to fund its current operations for at least the next twelve months from the issuance of the financial statements.

2. Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

The unaudited interim condensed consolidated financial statements of the Company included herein have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) as found in the Accounting Standards Codification (ASC), Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB) and the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these financial statements should be read in conjunction with the financial statements as of and for the year ended December 31, 2021 and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 17, 2022 (the 2021 Annual Report on Form 10-K).

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements, and updated, as necessary, in this report. In the opinion of the Company's management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments that are necessary to present fairly the Company's financial position as of March 31, 2022, the results of its operations for the three months ended March 31, 2022 and 2021, stockholder's equity for the three months ended March 31, 2022 and 2021 and cash flows for three months ended March 31, 2022 and 2021. Such adjustments are of a normal and recurring nature. The results for the three months ended March 31, 2022 are not necessarily indicative of the results for the year ending December 31, 2022 or for any future period.

The accompanying unaudited interim condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Blueprint Medicines Security Corporation, which is a Massachusetts subsidiary created to buy, sell and hold securities, Blueprint Medicines (Switzerland) GmbH, Blueprint Medicines (Netherlands) B.V., Blueprint Medicines (UK) Ltd, Blueprint Medicines (Germany) GmbH, Blueprint Medicines (Spain) S.L., Blueprint Medicines (France) SAS, Blueprint Medicines (Italy) S.r.L., and Lengo Therapeutics, Inc. (Lengo), which was acquired on December 30, 2021. All intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and in developing the estimates and assumptions that are used in the preparation of the financial statements. Management must apply significant judgment in this process. Management's estimation process often may yield a range of potentially reasonable estimates and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: revenue recognition, inventory, operating lease right-of-use assets, operating lease liabilities, stock-based compensation expense, accrued expenses, and income taxes. The length of time and full extent to which the ongoing COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including revenues, expenses, reserves and allowances, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, subject to change and difficult to predict, including as a result of new information that may emerge concerning COVID-19, including the identification and spread of new variants, and the actions taken to contain or treat COVID-19, as well as the economic impact thereof on local, regional, national and international customers and markets. The Company considers the impact of COVID-19 while making the estimates within its consolidated financial statements and there may be changes to those estimates in future periods. Actual results may differ from these estimates. The Russian invasion of Ukraine has not had a material impact on the Company's business, results of operations and financial condition.

Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three months ended March 31, 2022 are consistent with those discussed in Note 2 to the consolidated financial statements in the 2021 Annual Report on Form 10-K.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on its condensed consolidated financial statements and disclosures.

Government assistance

In November 2021, the FASB issued ASU No. 2021-10, Government Assistance (Topic 832) – Disclosures by Business Entities about Government Assistance to add annual disclosure requirements related to transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy. The standard is effective for annual periods beginning after December 15, 2021, with early adoption permitted. The Company adopted the new standard on January 1, 2022. The adoption did not have a significant impact on the disclosures of the Company's condensed consolidated financial statements.

Reclassification

Certain items in the prior year's condensed consolidated financial statements have been reclassified to conform to the current presentation.

3. Marketable securities

Marketable securities consisted of the following at March 31, 2022 and December 31, 2021 (in thousands):

March 31, 2022	Amortized Cost	Unrealized Gain	Unrealized Losses	Fair Value
Marketable securities, available-for-sale:				
U.S. government agency securities	$ 498,420	$ —	(5,649)	$ 492,771
U.S. treasury obligations	368,440	1	(5,060)	363,381
Total	$ 866,860	$ 1	$ (10,709)	$ 856,152

December 31, 2021	Amortized Cost	Unrealized Gain	Unrealized Losses	Fair Value
Marketable securities, available-for-sale:				
U.S. government agency securities	$ 498,582	$ 21	$ (1,460)	$ 497,143
U.S. treasury obligations	328,801	—	(1,249)	327,552
Total	$ 827,383	$ 21	$ (2,709)	$ 824,695

As of March 31, 2022, the Company held 88 debt securities that were in an unrealized loss position with an aggregate fair value of $841.2 million. As of December 31, 2021, the Company held 74 debt securities that were in an unrealized loss position with an aggregate fair value of $750.5 million. As of March 31, 2022 and December 31, 2021, there were no securities held by the Company in an unrealized loss position for more than twelve months. The Company has the intent and ability to hold such securities until recovery. As a result, the Company did not record any charges for credit-related impairments for its marketable debt securities for the three months ended March 31, 2022 and 2021.

As of March 31, 2022, 33 securities with an aggregate fair value of $306.5 million had remaining maturities between one year and five years. As of December 31, 2021, 56 securities with an aggregate fair value of $557.5 million had remaining maturities between one year and five years.

The Company did not receive any proceeds from maturities of debt securities for the three months ended March 31, 2022 and received proceeds of $215.5 million from maturities of debt securities for the three months ended March 31, 2021. The Company did not realize any gains or losses from maturities of debt securities for the three months ended March 31, 2022 and 2021.

4. Fair Value of Financial Instruments

The following table summarizes cash equivalents and marketable securities measured at fair value on a recurring basis as of March 31, 2022 (in thousands):

Description	March 31, 2022	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$ 14,699	$ 14,699	$ —	$ —
Marketable securities, available-for-sale:				
U.S. government agency securities	492,771	—	492,771	—
U.S. treasury obligations	363,381	363,381	—	—
Total	$ 870,851	$ 378,080	$ 492,771	$ —

The following table summarizes cash equivalents and marketable securities measured at fair value on a recurring basis as of December 31, 2021 (in thousands):

Description	December 31, 2021	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$ 118,880	$ 118,880	$ —	$ —
Marketable securities, available-for-sale:				
U.S. government agency securities	497,143	—	497,143	—
U.S. treasury obligations	327,552	327,552	—	—
Total	$ 943,575	$ 446,432	$ 497,143	$ —

5. Product Revenue Reserves and Allowances

In January 2020, the U.S. Food and Drug Administration (FDA) approved AYVAKIT for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. In September 2020, the European Commission granted conditional marketing authorization to AYVAKYT as a monotherapy for the treatment of adult patients with unresectable or metastatic GIST harboring the PDGFRA D842V mutation. In June 2021, the FDA granted a subsequent approval for AYVAKIT, expanding the labeled indications to include adult patients with advanced systemic mastocytosis (Advanced SM), including aggressive SM (ASM), SM with an associated hematological neoplasm (SM-AHN) and mast cell leukemia (MCL). In March 2022, the European Commission expanded the marketing authorization for AYVAKYT to include the treatment of adult patients with ASM, SM-AHN, or MCL, after at least one systemic therapy.

In September 2020, the FDA granted accelerated approval of GAVRETO for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test. In December 2020, the FDA granted a subsequent accelerated approval for GAVRETO, expanding the labeled indications to include adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy, or with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

The Company recorded net product revenue from the U.S. product sales of GAVRETO in 2021 until it transferred, on July 1, 2021, certain responsibilities associated with product sales to customers, pricing and distribution matters related to U.S. product sales of GAVRETO to its collaboration partner. The Company did not record any net product revenue from product sales of GAVRETO subsequent to this transition date. For additional information, see Note 9, *Collaboration and License Agreements*.

The following table summarizes revenue recognized from product sales for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
AYVAKIT/AYVAKYT	$ 23,841	$ 7,127
GAVRETO	—	1,828
Total product revenue	$ 23,841	$ 8,955

The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31	
	2022	2021
Beginning balance at January 1	$ 4,345	$ 1,192
Provision related to product sales	4,581	1,582
Adjustment related to prior periods sales	(308)	—
Credits and payments made	(2,654)	(774)
Ending balance at March 31	$ 5,964	$ 2,000

The total reserves that are included in the Company's unaudited condensed consolidated balance sheets as of March 31, 2022 and December 31, 2021, are summarized as follows (in thousands):

	March 31, 2022	December 31, 2021
Reduction of accounts receivable, net	$ 870	$ 419
Component of accrued expenses	5,094	3,926
Total revenue-related reserves	$ 5,964	$ 4,345

6. Inventory

Capitalized inventory consists of the following at March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Raw materials	$ 16,606	$ 10,788
Work in process	18,619	17,702
Finished goods	2,270	3,916
Total	$ 37,495	$ 32,406

Balance sheet classification

	March 31, 2022	December 31, 2021
Inventory	$ 30,145	$ 21,817
Other assets	7,350	10,589
Total	$ 37,495	$ 32,406

Inventory amounts written down as a result of excess, obsolescence, unmarketability or other reasons are charged to cost of sales. The Company did not recognize any such write-down for the three months ended March 31, 2022 and 2021. Long-term inventory, which primarily consists of work in process and raw materials, is included in other assets in the unaudited condensed consolidated balance sheets.

7. Restricted Cash

At March 31, 2022 and December 31, 2021, $5.2 million and $5.2 million, respectively, of the Company's cash is restricted by a bank primarily related to security deposits for the Company's building lease agreements.

8. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2022	December 31, 2021
Research, development and commercial contract costs	$ 57,431	$ 68,164
Employee compensation	13,613	29,166
Accrued professional fees	14,947	12,611
Revenue-related reserves	5,094	3,926
Other	9,613	7,962
Total	$ 100,698	$ 121,829

9. Collaboration and License Agreements

Proteovant

On February 26, 2022, the Company entered into an exclusive collaboration agreement (the Proteovant collaboration agreement) with Oncopia Therapeutics, Inc., d/b/a Proteovant Therapeutics, Inc., (Proteovant), pursuant to which the parties will jointly research and advance up to two novel protein degrader therapies into development candidates, as well as up to two additional novel protein degrader target programs as may be mutually agreed to by the Company and Proteovant (each a target program). On a target program-by-target program basis, the Company will have an exclusive option to obtain a worldwide, exclusive license to develop and commercialize any licensed compound and licensed product under each target program. Proteovant will have the right to opt into the global development and U.S. commercialization of certain licensed compounds and licensed products under the second target program that the Company options, and if the parties add additional target programs, Proteovant will have the same opt-in right for the fourth target program that the Company options.

The Company paid Proteovant an upfront payment of $20.0 million in connection with the execution of the agreement and Proteovant will be eligible to receive up to an additional $632.0 million in contingent milestone payments including specified research, development, regulatory and commercialization milestones and tiered percentage royalties on a licensed product-by-licensed product basis ranging from the mid- to high-single digits on net sales on the first two target programs, subject to adjustment in specified circumstances. If Proteovant opts in to the second target program, the parties will split profits and losses of that program equally in the U.S. along with development costs and the milestone payments for the program will be reduced accordingly. Proteovant will be eligible to receive milestone payments and royalties on ex-U.S. sales. In addition, the parties may jointly extend the collaboration, with the same structure and financial terms, to two additional program targets through additional funding by the Company.

The Company concluded that Proteovant is providing the Company with research services throughout the period until the Company can exercise its option to obtain a worldwide, exclusive license to develop and commercialize any licensed compound. Therefore, the Company recorded the $20.0 million upfront payment as an asset on the unaudited condensed consolidated financial statements and will record it as research and development expense over the expected research period. During the three months ended March 31, 2022, the Company recorded research and development expense of $0.5 million under the Proteovant collaboration agreement. The Company will reevaluate the research period at the end of each reporting period and as any changes in circumstances occur, and if necessary, the Company will adjust its estimate of expected research period accordingly. Each research and development milestone payment will be accrued and expensed when probable.

Zai Lab

On November 8, 2021, the Company entered into a collaboration (the Zai Lab agreement) with Zai Lab (Shanghai) Co., Ltd., (Zai Lab), pursuant to which the Company granted Zai Lab exclusive rights to develop and commercialize the Company's drug candidates BLU-701 and BLU-945 for the treatment of EGFR-driven non-small cell lung cancer in Greater China, including Mainland China, Hong Kong, Macau and Taiwan (collectively, the Zai Lab territory), either as a monotherapy or as part of a combination therapy. The Company retains exclusive rights to the licensed products outside the Zai Lab territory.

Under the Zai Lab agreement, the Company received an upfront cash payment of $25.0 million and, in addition to the upfront payment received, the Company is eligible to receive up to $590.0 million in contingent payments, including specified development, regulatory and sales-based milestones and tiered percentage royalties on a licensed product-by-licensed product basis ranging from the low-teens to mid-teens on annual net sales of each licensed product in the Zai Lab territory, subject to adjustment in specified circumstances. Zai Lab will be responsible for costs related to clinical trials in the Zai Lab territory, other than the specified shared services costs as defined in the Zai Lab agreement which will be shared by the Company and Zai Lab.

Pursuant to the terms of the Zai Lab agreement, Zai Lab is responsible for conducting all development and commercialization activities in the Zai Lab territory related to the licensed drug candidates. In addition, under the Zai Lab agreement, each party has granted the other party specified intellectual property licenses to enable the other party to perform its obligations and exercise its rights under the Zai Lab agreement, including license grants to enable each party to conduct research, development and commercialization activities pursuant to the terms of the Zai Lab agreement.

The Zai Lab agreement will continue on a licensed product-by-product and region-by-region basis until the later of (i) the 12th anniversary of the date of the first commercial sale of a licensed product in the Zai Lab territory, (ii) the date of expiration of the last valid patent claim related to the Company's patent rights of the product in the Zai Lab territory, and (iii) the expiration of the last regulatory exclusivity for that product in a region in the Zai Lab territory. Zai Lab may terminate the agreement for convenience by giving a written notice after the second anniversary of the effective date (a) at least 12 months after the date of notice, in the event such notice is given after the first commercial sale of a licensed product in the Zai Lab territory or (b) at least nine months after the date of such notice, in the event such notice is given prior to the first commercial sale of the first licensed product in the Zai Lab territory. Either party may terminate the Zai Lab agreement for the other party's uncured material breach or insolvency. Upon termination, all licenses and all other rights granted by the Company to Zai Lab will terminate. Each party will retain its joint ownership interests in any joint collaboration technology.

The Company evaluated the Zai Lab agreement to determine whether it is a collaborative arrangement in the scope of ASC 808. The Company concluded that the Zai Lab agreement is a collaborative agreement under ASC 808 as both parties are active participants in the clinical trials and are exposed to significant risks and rewards of those activities under the Zai Lab agreement. The Company determined that the Zai Lab agreement contained two material components: (i) licenses granted to Zai Lab to exploit and develop each licensed product in the Zai Lab territory and related activities in the Zai Lab territory, including manufacturing, and (ii) the parties' participation in the global development of the licensed products. The Company used the criteria specified in ASC 606 to determine which of the components of the Zai Lab agreement are performance obligations with a customer and concluded that Zai Lab is the Company's customer for the licenses and related activities in the Zai Lab territory under ASC 606. The global development activities under the agreement does not present a transaction with a customer and the payments received by the Company for global development activities, including manufacturing, are accounted for as a reduction of related expenses. During the three months ended March 31, 2022, no material reduction of expenses was recorded from the Zai Lab agreement.

The Company evaluated the Zai Lab territory specific licenses and related activities under ASC 606 as these transactions are considered transactions with a customer and identified three material promises at the outset of the Zai Lab agreement, which consists of the following for each licensed product: (1) the exclusive license, (2) the initial know-how transfer and (3) manufacturing activities related to development and commercial supply of the licensed product in the Zai Lab territory. The Company determined that the exclusive license and the initial know-how transfer were not distinct from each other, as the exclusive license has limited value without the corresponding know-how transfer. As such, for the purposes of ASC 606, the Company determined that these two material promises, the exclusive license and the initial know-how, should be combined into one distinct performance obligation. The Company further evaluated the material promise associated with manufacturing activities related to development and commercial supply of the licensed products in the Zai Lab territory, given Zai Lab is not obligated to purchase any minimum amount or quantities of the development and commercial supply from the Company, the Company concluded that, for the purpose of ASC 606, the provision of manufacturing activities related to development and commercial supply of the licensed product in Zai Lab territory was an option but not a performance obligation of the Company at the inception of the Zai Lab collaboration agreement and will be accounted for if and when exercised. The Company also concluded that there is no separate material right in connection with the development and commercial supply of the licensed product, as the expected pricing was not issued at a significant and incremental discount. Therefore, the manufacturing activities were excluded as performance obligation at the outset of the arrangement.

The Company evaluated the license under ASC 606 and concluded that the license is a functional intellectual property license. The Company determined that Zai Lab benefited from the license along with the initial know-how transfer at the time of grant, and therefore the related performance obligation is satisfied at a point in time. Additionally, the Company is entitled to sales milestones and royalties from Zai Lab upon future sales of the licensed products in the Zai Lab territory, and revenue will be recognized when the related sales occur. Costs that are incurred associated with Zai Lab territory specific activities are reimbursable from Zai and are recognized as revenue. During the three months ended March 31, 2022, no material revenue was recorded related to Zai Lab territory specific activities in the unaudited condensed consolidated financial statements.

For the purposes of ASC 606, the transaction price of the Zai Lab agreement as of the outset of the arrangement was determined to be $25.0 million, which consisted of the upfront cash payment. The other potential milestone payments that the Company is eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained based on the probability of achievement. The Company satisfied the performance obligation upon delivery of the licenses and initial know-how transfer and recognized the upfront payment of $25.0 million as revenue during the year ended December 31, 2021.

The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and if necessary, the Company will adjust its estimate of the transaction price, and any addition to the transaction price would be recognized as revenue when it becomes probable that inclusion would not lead to a significant revenue reversal.

Roche – Pralsetinib Collaboration

On July 13, 2020, the Company entered into a collaboration agreement (the Roche pralsetinib collaboration agreement) with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively, Roche), pursuant to which the Company granted Roche exclusive rights to develop and commercialize the Company's drug candidate pralsetinib worldwide, excluding the CStone territory (as defined below), and a co-exclusive license in the U.S. to develop and commercialize pralsetinib. In addition, Roche has the right to opt in to a next-generation RET compound co-developed by the Company and Roche.

Under the Roche pralsetinib collaboration agreement, the Company received an upfront cash payment of $675.0 million, and through March 31, 2022, the Company has received an aggregate of $105.0 million in specified regulatory and commercialization milestones. In addition to the upfront and milestone payments received through March 31, 2022, the Company is eligible to receive up to $822.0 million in contingent payments, including specified development, regulatory and sales-based milestones for pralsetinib and any licensed product containing a next-generation RET compound.

In the U.S., the Company and Roche agreed to work together to co-commercialize pralsetinib and equally share responsibilities, profits and losses. In addition, the Company is eligible to receive tiered royalties ranging from high-teens to mid-twenties on annual net sales of pralsetinib outside the U.S., excluding Greater China (the Roche territory). The Company and Roche have also agreed to co-develop pralsetinib globally in RET-altered solid tumors, including non-small cell lung cancer, medullary thyroid carcinoma and other thyroid cancers, as well as other solid tumors. The Company and Roche will share global development costs for pralsetinib at a rate of 45 percent for the Company and 55 percent for Roche up to a specified amount of aggregate joint development costs, after which the Company's share of global development costs for pralsetinib will be reduced by a specified percentage. The Company and Roche will also share specified global development costs for any next-generation RET compound co-developed under the collaboration in a similar manner.

Unless earlier terminated in accordance with its terms, the Roche pralsetinib collaboration agreement will expire on a licensed product-by-licensed product basis (i) in the U.S. upon the expiration of the gross profit sharing term for such licensed product and (ii) outside the U.S. on a country-by-country basis at the end of the applicable royalty term for such licensed product. Roche may terminate the agreement in its entirety or on a licensed product-by-licensed product or country-by-country basis subject to certain notice periods. Either party may terminate the Roche pralsetinib collaboration agreement for the other party's uncured material breach or insolvency. Subject to the terms of the Roche pralsetinib collaboration agreement, effective upon termination of the agreement, the Company is entitled to retain specified licenses to be able to continue to exploit the licensed products.

In connection with the Roche collaboration agreement, on July 13, 2020, the Company also entered into a stock purchase agreement with Roche Holdings, Inc. (Roche Holdings) pursuant to which the Company issued and sold an aggregate of 1,035,519 shares of common stock to Roche Holdings at a purchase price of $96.57 per share and received an aggregate of $100.0 million in the third quarter of 2020. The closing for a minority portion of the equity investment occurred following the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions.

The Company considered the ASC 606 criteria for combining contracts and determined that the Roche pralsetinib collaboration agreement and stock purchase agreement should be combined into a single contract because they were negotiated and entered into in contemplation of one another. The Company accounted for the common stock issued to Roche Holdings based on the fair market value of the common stock on the dates of issuance. The fair market value of the common stock issued to Roche Holdings was $79.3 million, based on the closing price of the Company's common stock on the dates of issuance, resulting in a $20.7 million premium. The Company determined that the premium paid by Roche Holdings for the common stock should be attributed to the transaction price of the Roche pralsetinib collaboration agreement.

The Company determined that the Roche pralsetinib collaboration agreement contained four material components: (i) licenses granted to Roche to develop and commercialize pralsetinib worldwide, excluding the CStone territory (pralsetinib license); (ii) the Roche territory-specific commercialization activities for pralsetinib, including manufacturing (Roche territory activities); (iii) the parties' joint development activities for pralsetinib worldwide, excluding the CStone territory; and (iv) the parties' joint commercialization activities for pralsetinib in the U.S. The Company considered the guidance in ASC 606 to determine which of the components of the Roche pralsetinib collaboration agreement are performance obligations with a customer and concluded that the pralsetinib license and the Roche territory activities are within the scope of ASC 606 because Roche is the Company's customer in those transactions.

The Company evaluated the Roche pralsetinib license under ASC 606 and concluded that the pralsetinib license is a functional intellectual property license and is a distinct performance obligation. The Company determined that Roche benefited from the pralsetinib license at the time of grant, and therefore the related performance obligation is satisfied at a point in time.

The Company evaluated the Roche territory activities under ASC 606 and identified one material promise associated with manufacturing activities related to development and commercial supply of pralsetinib in the Roche territory for up to 24 months. Given that Roche is not obligated to purchase any minimum amount or quantities of the development and commercial supply from the Company, the Company concluded that, for the purpose of ASC 606, the provision of manufacturing activities related to development and commercial supply of pralsetinib in Roche territory was an option but not a performance obligation of the Company at the inception of the Roche collaboration agreement and will be accounted for if and when exercised. The Company also concluded that there is no separate material right in connection with the development and commercial supply of pralsetinib, as the expected pricing was not issued at a significant and incremental discount. Therefore, the manufacturing activities were excluded as performance obligations at the outset of the arrangement. Additionally, the Company is entitled to sales milestones and royalties from Roche upon future sales of pralsetinib in the Roche territory, and revenue are recognized when the related sales occur. Costs that are incurred associated with the Roche territory activities are reimbursable from Roche and are recognized as revenue.

For the purposes of ASC 606, the transaction price of the Roche collaboration agreement at the outset of the arrangement was determined to be $695.7 million, which consisted of the upfront cash payment of $675.0 million and the $20.7 million premium on the sale of common stock to Roche Holdings, which was allocated to the performance obligation related to the pralsetinib licenses. Through March 31, 2022, the Company has achieved an aggregate of $105.0 million in specified regulatory and commercialization milestones and added the $105.0 million to the estimated transaction price of the Roche pralsetinib agreement. The other potential milestone payments that the Company is eligible to receive under the Roche pralsetinib agreement have been excluded from the transaction price, as all the remaining milestone amounts were fully constrained based on the probability of achievement. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and if necessary, the Company will adjust its estimate of the transaction price, and any addition

to the transaction price would be recognized as revenue when it becomes probable that inclusion would not lead to a significant revenue reversal.

The following table summarizes revenue recognized under the Roche pralsetinib collaboration during the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Manufacturing and research and development services related to Roche territory-specific activities	656	1,772
Royalty revenue	286	—
Total Roche pralsetinib collaboration revenue	$ 942	$ 1,772

For the parties' participation in global development for pralsetinib and the U.S. commercialization activities for GAVRETO, the Company concluded that those activities and cost-sharing payments related to such activities are within the scope of ASC 808, as both parties are active participants in the development, manufacturing and commercialization activities and are exposed to significant risks and rewards of those activities under the Roche pralsetinib collaboration agreement. Payments to or reimbursements from Roche related to the global development activities are accounted for as an increase to or reduction of research and development expenses. Prior to July 1, 2021, the Company was the principal for product sales to customers in the U.S. and recognized revenues on sales to third parties in product revenue, net in its consolidated statements of operations and comprehensive loss. On July 1, 2021, Roche took over certain responsibilities associated with product sales to customers, pricing and distribution matters for GAVRETO in the U.S. and became the principal for recording product sales to customers in the U.S., and the Company recognized its portion of the commercial losses sharing as collaboration loss sharing in its consolidated statements of operations and comprehensive loss.

The following table summarizes the amount recognized from collaboration loss sharing after Roche became the principal for product sales of GAVRETO to customers in the U.S. (in thousands):

	Three Months Ended March 31,	
	2022	2021
The Company's share of loss in the U.S. for pralsetinib	$ 3,265	$ —

The following table summarizes the amounts recognized as reductions to selling, general and administrative expenses related to the commercialization of GAVRETO in the U.S., and reductions to research and development expenses related to global development activities for pralsetinib under the Roche pralsetinib collaboration during the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Reductions to selling, general and administrative expenses	$ 4,832	$ 3,003
Reductions to research and development expenses	$ 10	$ 4,082

The following table summarizes the contract assets associated with the Roche pralsetinib collaboration as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Accounts receivable, net	$ 1,104	$ 2,679
Unbilled accounts receivable	$ 2,643	$ 6,802

Clementia

On October 15, 2019, the Company entered into a license agreement (the Clementia agreement) with Clementia Pharmaceuticals, Inc. (Clementia), a wholly-owned subsidiary of Ipsen S.A. Under the Clementia agreement, the Company granted an exclusive, worldwide, royalty-bearing license to Clementia to develop and commercialize BLU-782, the Company's oral, highly selective investigational ALK2 inhibitor in Phase 1 clinical development for the treatment of fibrodysplasia ossificans progressiva (FOP), as well as specified other compounds related to the BLU-782 program.

Under the Clementia agreement, the Company received an upfront cash payment of $25.0 million and through March 31, 2022, the Company has received an aggregate of $50.0 million in cash milestone payments. Subject to the terms of the Clementia agreement, in addition to the upfront and milestone payments received through March 31, 2022, the Company is eligible to receive up to $460.0 million in contingent payments, including specified development, regulatory and sales-based milestones for licensed products. In addition, Clementia is obligated to pay to the Company royalties on aggregate annual worldwide net sales of licensed products at tiered percentage rates ranging from the low- to mid-teens, subject to adjustment in specified circumstances under the Clementia agreement, and to purchase specified manufacturing inventory from the Company for a total of $1.5 million.

Unless earlier terminated in accordance with the terms of the Clementia agreement, the agreement will expire on a country-by-country, licensed product-by-licensed product basis on the date when no royalty payments are or will become due. Clementia may terminate the agreement at any time on or after the second anniversary of the effective date of the agreement upon at least 12 months' prior written notice to the Company, which cannot be delivered before the first anniversary of the effective date. Either party may terminate the agreement for the other party's uncured material breach or insolvency and in certain other circumstances agreed to by the parties. In certain termination circumstances, the Company is entitled to retain specified licenses to be able to continue to exploit the Clementia licensed products.

The Company evaluated the Clementia agreement under ASC 606, as the agreement represented a transaction with a customer. The Company identified the following material promises under the agreement: (1) the exclusive license to develop, manufacture and commercialize BLU-782; (2) the technology transfer of BLU-782 program; (3) the transfer of existing manufacturing inventory; and (4) the transfer of in-process manufacturing inventory. In addition, the Company determined that the exclusive license and technology transfer were not distinct from each other, as the exclusive license has limited value without the corresponding technology transfer. As such, for the purposes of ASC 606, the Company determined that these four material promises, described above, should be combined into three performance obligations: (1) the exclusive license and the technology transfer; (2) the transfer of existing manufacturing inventory; and (3) the transfer of in-process manufacturing inventory.

The Company determined that the transaction price as of the outset of the arrangement was $46.5 million, which consisted of the upfront amount of $25.0 million, the $20.0 million cash milestone payment received in the third quarter of 2020, the purchase of existing manufacturing inventory of $1.2 million and the purchase of in-process manufacturing inventory of $0.3 million. The transaction price was allocated to the three performance obligations on a relative stand-alone selling price basis. The Company satisfied the performance obligations upon delivery of the license and completion of the technology transfer and inventory transfers. During 2019, the Company completed the delivery of the license, the technology transfer and the transfer of existing manufacturing inventory and recognized a total of $46.2 million as revenue.

During the three months ended March 31, 2022, cash consideration associated with an achieved development milestone of $30.0 million was added to the estimated transaction price for the Clementia agreement and recognized as revenue. The other potential milestone payments that the Company is eligible to receive were excluded from the transaction price, as the amounts were fully constrained based on the probability of achievement. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and if necessary, the Company will adjust its estimate of the transaction price, and any addition to the transaction price would be recognized as revenue when it becomes probable that inclusion would not lead to a significant revenue reversal.

During the three months ended March 31, 2021, no material revenue was recognized from the Clementia collaboration. There was no revenue deferred as a contract liability associated with the Clementia agreement as of March 31, 2022 and December 31, 2021.

CStone Pharmaceuticals

On June 1, 2018, the Company entered into a collaboration and license agreement (the CStone agreement) with CStone Pharmaceuticals (CStone) pursuant to which the Company granted CStone exclusive rights to develop and commercialize the Company's drug candidates avapritinib, pralsetinib and fisogatinib, including back-up forms and certain other forms thereof, in Mainland China, Hong Kong, Macau and Taiwan (each, a CStone region and collectively, the CStone territory), either as a monotherapy or as part of a combination therapy.

The Company received an upfront cash payment of $40.0 million, and through March 31, 2022, the Company has achieved an aggregate of $27.0 million in milestones under this collaboration. Subject to the terms of the CStone agreement, in addition to the upfront payments received and milestones achieved through March 31, 2022, the Company will be eligible to receive up to $319.0 million in contingent payments, including specified development, regulatory and sales-based milestones for licensed products. In addition, CStone will be obligated to pay the Company tiered percentage royalties on a licensed product-by-licensed product basis ranging from the mid-teens to low twenties on annual net sales of each licensed product in the CStone territory, subject to adjustment in specified circumstances. CStone will be responsible for costs related to the development of the licensed products in the CStone territory, other than specified costs related to the development of fisogatinib as a combination therapy in the CStone territory that will be shared by the Company and CStone.

Pursuant to the terms of the CStone agreement, CStone is responsible for conducting all development and commercialization activities in the CStone territory related to the licensed products. Subject to specified exceptions, during the term of the CStone agreement, each party has agreed that neither it nor its affiliates will conduct specified development and commercialization activities in the CStone territory related to selective inhibitors of FGFR4, KIT, PDGFRA and RET. In addition, under the CStone agreement, each party has granted the other party specified intellectual property licenses to enable the other party to perform its obligations and exercise its rights under the CStone agreement, including license grants to enable each party to conduct research, development and commercialization activities pursuant to the terms of the CStone agreement.

The CStone agreement will continue on a licensed product-by-licensed product and CStone region-by-CStone region basis until the later of (i) 12 years after the first commercial sale of a licensed product in a CStone region in the CStone territory and (ii) the date of expiration of the last valid patent claim related to the Company's patent rights or any joint collaboration patent rights for the licensed product that covers the composition of matter, method of use or method of manufacturing such licensed product in such region. Subject to the terms of the CStone agreement, CStone may terminate the CStone agreement in its entirety or with respect to one or more licensed products for convenience by providing written notice to the Company, and CStone may terminate the CStone agreement with respect to a licensed product for convenience at any time by providing written notice to the Company following the occurrence of specified events. In addition, the Company may terminate the CStone agreement under specified circumstances if CStone or certain other parties challenges the Company's patent rights or any joint collaboration patent rights or if CStone or its affiliates do not conduct any material development or commercialization activities with respect to one or more licensed products for a specified period of time, subject to specified exceptions. Either party may terminate the CStone agreement for the other party's uncured material breach or insolvency. In certain termination circumstances, the parties are entitled to retain specified licenses to be able to continue to exploit the licensed products, and in the event of termination by CStone for the Company's uncured material breach, the Company will be obligated to pay CStone a low single digit percentage royalty on a licensed product-by-licensed product basis on annual net sales of such licensed product in the CStone territory, subject to a cap and other specified exceptions.

The Company evaluated the CStone agreement to determine whether it is a collaborative arrangement for purposes of ASC 808. The Company determined that there were two material components of the CStone agreement: (i) the CStone territory-specific license and related activities in the CStone territory, and (ii) the parties' participation in global development of the licensed products. The Company concluded that the CStone territory-specific license and related activities in the CStone territory are not within the scope of ASC 808 because the Company is not exposed to significant risks and rewards. The Company concluded that CStone is a customer with regard to the component that

includes the CStone territory-specific license and related activities in CStone territory, which include manufacturing. For the parties' participation in global development of the licensed products, the Company concluded that the research and development activities and cost-sharing payments related to such activities are within the scope of ASC 808 as both parties are active participants exposed to the risk of the activities under the CStone agreement. The Company concluded that CStone is not a customer with regard to the global development component in the context of the CStone agreement. Therefore, payments received by the Company for global development activities under the CStone agreement, including manufacturing, are accounted for as a reduction of related expenses.

A summary of manufacturing and research and development services related to the global development activities, net of expenses payable to CStone during the three months ended March 31, 2022 and 2021 is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Manufacturing and research and development services related to global development activities, net of expenses payable to CStone	$ 488	$ 739

The Company evaluated the CStone territory-specific license and related activities in the CStone territory under ASC 606, as these transactions are considered transactions with a customer. The Company identified the following material promises under the arrangement: (1) the three exclusive licenses granted in the CStone territory to develop, manufacture and commercialize the three licensed products; (2) the initial know-how transfer for each licensed product; (3) manufacturing activities related to development and commercial supply of the licensed products; (4) participation in the joint steering committee (JSC) and joint project teams (JPT); (5) regulatory responsibilities; and (6) manufacturing technology and continuing know-how transfers. The Company determined that each licensed product is distinct from the other licensed products. In addition, the Company determined that the exclusive licenses and initial know-how transfers for each licensed product were not distinct from each other, as each exclusive license has limited value without the corresponding initial know-how transfer. For purposes of ASC 606, the Company determined that participation on the JSC and JPTs, the regulatory responsibilities and the manufacturing technology and continuing know-how transfers are qualitatively and quantitatively immaterial in the context of the CStone agreement and therefore are excluded from performance obligations. As such, the Company determined that these six material promises, described above, should be combined into one performance obligation for each of the three candidates.

The Company evaluated the provision of manufacturing activities related to development and commercial supply of the licensed products as an option for purposes of ASC 606 to determine whether these manufacturing activities provide CStone with any material rights. The Company concluded that the manufacturing activities were not issued at a significant and incremental discount, and therefore do not provide CStone with any material rights. As such, the manufacturing activities are excluded as performance obligations at the outset of the arrangement.

Based on these assessments, the Company identified three distinct performance obligations at the outset of the CStone agreement, which consists of the following for each licensed product: (1) the exclusive license and (2) the initial know-how transfer.

Under the CStone agreement, in order to evaluate the transaction price for purposes of ASC 606, the Company determined that the upfront amount of $40.0 million constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, which was allocated to the three performance obligations. The potential milestone payments that the Company is eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained based on the probability of achievement. The Company satisfied the performance obligations upon delivery of the licenses, initial know-how transfers and product trademark and recognized the upfront payment of $40.0 million as revenue during the year ended December 31, 2018.

During the three months ended March 31, 2022 and 2021, cash consideration associated with achieved regulatory and development milestones of $4.0 million and $9.0 million, respectively, were added to the estimated transaction price for the CStone agreement and recognized as revenue in such periods. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and if necessary, the Company will adjust its estimate of the transaction price, and any addition to

the transaction price would be recognized as revenue when it becomes probable that inclusion would not lead to a significant revenue reversal.

In 2021, the Company entered into commercial supply agreements and an avapritinib manufacturing technology transfer agreement with CStone related to supply of drug substance of avapritinib and drug product of avapritinib and pralsetinib to assist CStone's commercialization activities conducted specifically for the CStone territory. During the three months ended March 31, 2022, the Company entered into a pralsetinib manufacturing technology transfer agreement with CStone related to supply of drug substance of pralsetinib. The manufacturing activities in these agreements were considered as distinct performance obligations from the CStone collaboration agreement and collaboration revenue is recognized upon delivery of the drug substance and drug product to CStone.

A summary of revenue recognized under the CStone agreement during the three months ended March 31, 2022 and 2021 is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
License milestone revenue	$ 4,000	$ 9,000
Manufacturing services and royalty revenue related to CStone territory-specific activities	5,212	271
Total CStone collaboration revenue	$ 9,212	$ 9,271

The following table presents the contract assets associated with the CStone collaboration as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Accounts receivable, net	$ 12,233	$ 8,164
Unbilled accounts receivable	$ 853	$ 5,034

As of March 31, 2022, the Company had $4.6 million of deferred revenue as a contract liability associated with the CStone collaboration. This contract liability results primarily from advance payments made by CStone in connection with commercial supply of pralsetinib for the CStone territory. The contract liability associated with the CStone collaboration was $4.8 million at December 31, 2021.

Roche – Immunotherapy Collaboration

In March 2016, the Company entered into a collaboration and license agreement (as amended, the Roche immunotherapy agreement) with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, Roche) for the discovery, development and commercialization of small molecule therapeutics targeting kinases believed to be important in cancer immunotherapy (including BLU-852, a development candidate for the kinase target MAP4K1, which is believed to play a role in T cell regulation), as single products or possibly in combination with other therapeutics.

Under the Roche immunotherapy agreement, Roche was originally granted up to five option rights to obtain an exclusive license to exploit products derived from the collaboration programs in the field of cancer immunotherapy. Such option rights are triggered upon the achievement of Phase 1 proof-of-concept. As a result of amendments to the Roche immunotherapy agreement in prior reporting periods, the Company and Roche are currently conducting activities for up to two programs under the collaboration. For one of the two collaboration programs, if Roche exercises its option, Roche will receive worldwide, exclusive commercialization rights for the licensed product. For the other collaboration program, if Roche exercises its option, the Company will retain commercialization rights in the U.S. for the licensed product, and Roche will receive commercialization rights outside of the U.S. for the licensed product. The Company will also retain worldwide rights to any products for which Roche elects not to exercise its applicable option.

Prior to Roche's exercise of an option, the Company will have the lead responsibility for drug discovery and preclinical development of all collaboration programs. In addition, the Company will have the lead responsibility for the

conduct of all Phase 1 clinical trials other than those Phase 1 clinical trials for any product in combination with Roche's portfolio of therapeutics, for which Roche will have the right to lead the conduct of such Phase 1 clinical trials. Pursuant to the Roche immunotherapy agreement, the parties will share the costs of Phase 1 development for each collaboration program. In addition, Roche will be responsible for post-Phase 1 development costs for each licensed product for which it retains global commercialization rights, and the Company and Roche will share post-Phase 1 development costs for each licensed product for which the Company retains commercialization rights in the U.S.

The Company received an upfront cash payment of $45.0 million, and through March 31, 2022, the Company has received an aggregate of $23.5 million in milestone payments under this collaboration. Subject to the terms of the Roche immunotherapy agreement, as amended, in addition to the upfront and milestone payments received through March 31, 2022, the Company is eligible to receive up to approximately $319.3 million in contingent option fees and milestone payments related to specified research, preclinical, clinical, regulatory and sales-based milestones. In addition, for any licensed product for which Roche retains worldwide commercialization rights, the Company will be eligible to receive tiered royalties ranging from low double-digits to high-teens on future net sales of the licensed product. For any licensed product for which the Company retains commercialization rights in the U.S., the Company and Roche will be eligible to receive tiered royalties ranging from mid-single-digits to low double-digits on future net sales in the other party's respective territories in which it commercializes the licensed product. The upfront cash payment and any payments for milestones, option fees and royalties are non-refundable, non-creditable and not subject to set-off.

The Roche immunotherapy agreement will continue until the date when no royalty or other payment obligations are or will become due, unless earlier terminated in accordance with the terms of the Roche immunotherapy agreement. Prior to its exercise of its first option, Roche may terminate the Roche immunotherapy agreement at will, in whole or on a collaboration target-by-collaboration target basis, upon 120 days' prior written notice to the Company. Following its exercise of an option, Roche may terminate the Roche immunotherapy agreement at will, in whole, on a collaboration target-by-collaboration target basis, on a collaboration program-by-collaboration program basis or, if a licensed product has been commercially sold, on a country-by-country basis, (i) upon 120 days' prior written notice if a licensed product has not been commercially sold or (ii) upon 180 days' prior written notice if a licensed product has been commercially sold. Either party may terminate the Roche immunotherapy agreement for the other party's uncured material breach or insolvency and in certain other circumstances agreed to by the parties. In certain termination circumstances, the Company is entitled to retain specified licenses to be able to continue to exploit the licensed products.

The Company assessed this arrangement in accordance with ASC 606 upon the adoption of the new standard on January 1, 2018, and concluded that the contract counterparty, Roche, is a customer prior to the exercise, if any, of an option by Roche. The Company identified the following material promises under the arrangement: (1) a non-transferable, sub-licensable and non-exclusive license to use the Company's intellectual property and collaboration compounds to conduct research activities; (2) research and development activities through Phase 1 clinical trials under the research plan; (3) five option rights for licenses to develop, manufacture, and commercialize the collaboration targets; (4) participation on a joint research committee (JRC) and joint development committee (JDC); and (5) regulatory responsibilities under Phase 1 clinical trials. The Company determined that the license and research and development activities were not distinct from another, as the license has limited value without the performance of the research and development activities. Participation on the JRC and JDC to oversee the research and development activities was determined to be quantitatively and qualitatively immaterial and therefore is excluded from performance obligations. The regulatory responsibilities related to filings and obtaining approvals related to the drugs that may result from each program do not represent separate performance obligations based on their dependence on the research and development efforts. As such, the Company determined that these promises should be combined into a single performance obligation.

The Company evaluated the option rights for licenses to develop, manufacture, and commercialize the collaboration targets to determine whether it provides Roche with any material rights. The Company concluded that the options were not issued at a significant and incremental discount, and therefore do not provide material rights. As such, they are excluded as performance obligations at the outset of the arrangement.

Based on these assessments, the Company identified one performance obligation at the outset of the Roche immunotherapy agreement, which consists of: (1) the non-exclusive license; (2) the research and development activities through Phase 1; and (3) regulatory responsibilities under Phase 1 clinical trials.

Under the Roche immunotherapy agreement, in order to evaluate the appropriate transaction price, the Company determined that as of January 1, 2018, the upfront amount of $45.0 million constituted the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, which was allocated to the single performance obligation. The option exercise payments that may be received are excluded from the transaction price until each customer option is exercised as it was determined that the options are not material rights. The potential milestone payments that the Company is eligible to receive prior to the exercise of the options were initially excluded from the transaction price, as all milestone amounts were fully constrained based on the probability of achievement. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

Through March 31, 2022, the Company has achieved an aggregate of $23.5 million in research milestones under this collaboration, and these amounts were added to the estimated transaction price and allocated to the existing performance obligation as it became probable that a significant reversal of cumulative revenue would not occur for each of the research milestones achieved. During the three months ended March 31, 2022, it was determined that Roche will initiate a Phase 1 clinical development plan for BLU-852, one of the ongoing programs, in combination with atezolizumab, an approved drug product commercialized by Roche, and pursuant to the Roche immunotherapy agreement, the Company will share the development cost up to $15.0 million. As a result, the Company reduced the aggregated transaction price of this collaboration from $68.5 million to $53.5 million and recorded its commitment of $15.0 million as a contract liability on its unaudited condensed consolidated financial statements.

The Company recognizes revenue associated with the performance obligation as the research and development services are provided using an input method, according to the costs incurred as related to the research and development activities on each program and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The amounts received that have not yet been recognized as revenue are deferred as a contract liability on the Company's consolidated balance sheet and will be recognized over the remaining research and development period until the performance obligation is satisfied. During the three months ended March 31, 2022, a reduction in the costs expected to be incurred in the future to satisfy certain performance obligations under the collaboration became probable as a result of Roche and the Company endorsing the Phase 1 clinical development plan for one of the ongoing programs in combination with Roche's product.

Because of the revision to the cost expected to be incurred to satisfy the performance obligation and the reduction of the $15.0 million payment commitment to Roche from the aggregated transaction price of $68.5 million, the Company recorded a cumulative revenue catch-up of $2.9 million during the three months ended March 31, 2022. A summary of revenue recognized or revenue reduced under the Roche immunotherapy agreement during the three months ended March 31, 2022 and 2021 is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Roche collaboration research and development services revenue	$ (1,947)	$ 1,537

During the three months ended March 31, 2022 and 2021, the Company recognized the following revenue due to the changes in the contract liability balances (in thousands):

	Three Months Ended March 31,	
	2022	2021
Amounts included in the contract liability at the beginning of the period	$ 1,010	$ 1,238

The following table summarizes the contract liability related to the Roche immunotherapy agreement as of March 31, 2022, and December 31, 2021 (in thousands):

	March 31, 2022			December 31, 2021		
	Current	Noncurrent	Total	Current	Noncurrent	Total
Deferred revenue	$ 5,026	$ 13,721	$ 18,747	$ 6,339	$ 25,066	$ 31,405
Accrued expenses	8,174	6,826	15,000	—	—	—

The research and development services related to the performance obligation are expected to be performed over a remaining period of approximately 3.0 years.

10. Stock-based compensation

2015 Stock Option and Incentive Plan

In 2015, the Company's board of directors and stockholders approved the 2015 Stock Option and Incentive Plan (the 2015 Plan), which replaced the Company's 2011 Stock Option and Grant Plan, as amended (the 2011 Plan). The 2015 Plan includes incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, performance share awards and cash-based awards. The Company initially reserved a total of 1,460,084 shares of common stock for the issuance of awards under the 2015 Plan. The 2015 Plan provides that the number of shares reserved and available for issuance under the 2015 Plan will be cumulatively increased on January 1 of each calendar year by 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or such lesser amount as specified by the compensation committee of the board of directors. For the calendar year beginning January 1, 2022, the number of shares reserved for issuance under the 2015 Plan was increased by 2,365,643 shares. In addition, the total number of shares reserved for issuance is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization. As of March 31, 2022, there were 4,078,826 shares available for future grant under the 2015 Plan.

2020 Inducement Plan

In March 2020, the Company's board of directors adopted the 2020 Inducement Plan (the Inducement Plan), pursuant to which the Company may grant, subject to the terms of the Inducement Plan and Nasdaq rules, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock-based awards. The Company initially reserved a total of 1,000,000 shares of common stock for the issuance of awards under the Inducement Plan. The number of shares reserved and available for issuance under the Inducement Plan can be increased at any time with the approval of the Company's board of directors. The Inducement Plan permits the board of directors or a committee thereof to use the stock-based awards available under the Inducement Plan to attract key employees for the growth of the Company. As of March 31, 2022, there were 246,341 shares available for future grant under the Inducement Plan.

Stock options

The following table summarizes the stock option activity for the three months ended March 31, 2022:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2021	5,682,022	$ 69.37
Granted	833,510	62.74
Exercised	(79,226)	16.35
Canceled	(90,131)	84.97
Outstanding at March 31, 2022	6,346,175	$ 68.93
Exercisable at March 31, 2022	3,633,252	$ 63.19

As of March 31, 2022, the total unrecognized compensation expense related to unvested stock option awards was $106.8 million, which is expected to be recognized over a weighted-average period of approximately 2.75 years.

Restricted stock units

The following table summarizes the restricted stock units activity for the three months ended March 31, 2022:

	Shares	Weighted-Average Grant Date Fair Value
Unvested shares at December 31, 2021	1,590,160	$ 83.85
Granted	652,511	62.09
Vested	(335,662)	79.18
Forfeited	(38,550)	84.46
Unvested shares at March 31, 2022	1,868,459	$ 77.06

As of March 31, 2022, the total unrecognized compensation expense related to unvested restricted stock units was $132.8 million, which is expected to be recognize over a weighted-average period of approximately 3.03 years.

2015 Employee Stock Purchase Plan

In 2015, the Company's board of directors and stockholders approved the 2015 Employee Stock Purchase Plan (the 2015 ESPP), which became effective upon the closing of the Company's initial public offering in May 2015. The Company initially reserved a total of 243,347 shares of common stock for issuance under the 2015 ESPP. The 2015 ESPP provides that the number of shares reserved and available for issuance under the 2015 ESPP will be cumulatively increased on January 1 of each calendar year by 1% of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or such lesser amount as specified by the compensation committee of the board of directors. For the calendar year beginning January 1, 2022, the number of shares reserved for issuance under the 2015 ESPP was increased by 591,410 shares.

Stock-based compensation expense

The Company recognized stock-based compensation expense totaling $23.4 million and $20.7 million for the three months ended March 31, 2022 and 2021, respectively. Stock-based compensation expense by award type included within the unaudited condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Stock options	$ 12,945	$ 14,141
Restricted stock units	10,385	6,795
Employee stock purchase plan	279	276
Subtotal	23,609	21,212
Capitalized stock-based compensation costs	(210)	(528)
Stock-based compensation expense included in total cost and operating expenses	$ 23,399	$ 20,684

Stock-based compensation expense, that is included in operating expenses, by classification within the unaudited condensed consolidated statements of operations and comprehensive loss is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 10,041	$ 8,946
Selling, general and administrative	13,358	11,738
Total	$ 23,399	$ 20,684

11. Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. For purposes of the dilutive net loss per share calculation, stock options, unvested restricted stock units and ESPP shares are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive; therefore, basic and diluted net loss per share were the same for all periods presented as a result of the Company's net loss.

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect (in thousands):

	Three Months Ended March 31,	
	2022	2021
Stock options	6,346	6,386
Restricted stock units	1,868	1,583
ESPP shares	24	19
Total	8,238	7,988

12. Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. The Company provides a valuation allowance when it is more likely than not that deferred tax assets will not be realized.

The realization of deferred income tax assets is dependent on the generation of sufficient taxable income during future periods in which temporary differences are expected to reverse. Where the realization of such assets does not meet the more likely than not criterion, the Company applies a valuation allowance against the deferred income tax asset under consideration. The valuation allowance is reviewed periodically and if the assessment of the more likely than not criterion changes, the valuation allowance is adjusted accordingly. As of March 31, 2022, the Company has a full valuation allowance applied against its U.S. and foreign deferred tax assets.

On March 11, 2021, President Joe Biden signed into law a relief and stimulus package known as the American Rescue Plan Act of 2021 (ARPA) stimulus package. While this Act provides various tax provisions including for example, extending the employee retention credit through the end of 2021, modifying the paid sick and family leave credits, repealing the worldwide interest allocation rules that were scheduled to take effect in 2021, and expanding the number of employees subject to the limit on the deduction for executive compensation under Section 162(m) beginning in 2027, among other things, based on the Company's initial review of the various business tax provisions offered in the ARPA along with having a valuation allowance on its U.S. deferred tax assets, it does not believe that there is an impact to the Company and as such the recording of a discrete item was not required during the three months ended March 31, 2022.

Effective January 1, 2022, a provision of the Tax Cuts and Jobs Act (TCJA) has taken effect creating a significant change to the treatment of research and experimental (R&E) expenditures under Section 174 of the IRC (Sec. 174 expenses). Historically, businesses have had the option of deducting Sec. 174 expenses in the year incurred or capitalizing and amortizing the costs over five years. The new TCJA provision, however, eliminates this option and will require Sec. 174 expenses associated with research conducted in the U.S to be capitalized and amortized over a five-year period. For expenses associated with research outside of the United States, Sec. 174 expenses will be capitalized and amortized over a 15-year period. The Company prepared an analysis of the tax impact of capitalizing and amortizing

these costs over the required periods and for calendar year 2022, it is expecting to be in a loss position after the estimated addback.

13. Leases

The Company's building leases are comprised of office and laboratory spaces under non-cancelable operating leases. The lease agreements contain various clauses for renewal at the Company's option, and the renewal options were not included in the calculation of the operating lease assets and the operating lease liabilities as the renewal options were not reasonably certain of being exercised as of March 31, 2022. The lease agreements do not contain residual value guarantees and the components of lease cost for the three months ended March 31, 2022 and 2021 were as follows (in thousands):

	Three Months Ended March 31,	
Operating leases:	2022	2021
Lease cost	$ 5,968	$ 4,722
Sublease income	(781)	(327)
Net lease cost	$ 5,187	$ 4,395

The Company has not entered into any material short-term leases or financing leases as of March 31, 2022.

Supplemental cash flow information related to leases for the three months ended March 31, 2022 and 2021 is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:	$ 3,882	$ 3,696
Lease liabilities arising from obtaining right-of-use assets:		
Operating leases	$ —	$ —

The weighted average remaining lease term and weighted average discount rate of the operating leases are as follows:

	Operating leases
Weighted average remaining lease term in years	7.6
Weighted average discount rate	7.4%

14. Commitments and Contingencies

Purchase Commitments Associated with Commercial Supply Agreements

In connection with the commercialization of AYVAKIT/AYVAKYT and GAVRETO, the Company has negotiated manufacturing agreements with certain vendors that require the Company to meet minimum purchase obligations on an annual basis. During the three months ended March 31, 2022, there were no material changes to the Company's contractual obligations described in Note 18 to the consolidated financial statements in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as they are incurred.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management that will require the Company, among other things, to indemnify them against certain liabilities that may arise from their status or service as directors or officers of the Company. The maximum potential amount of future payments that the Company could be required to make, or otherwise be liable for, under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of March 31, 2022 or December 31, 2021.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission (the SEC) on February 17, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results or timing of certain events could differ materially from the results or timing described in, or implied by, these forward-looking statements.

Overview

We are a global precision therapy company that is inventing life-changing medicines for people with cancer and blood disorders. Applying an approach that is both precise and agile, we create therapies that selectively target genetic drivers, with the goal of staying one step ahead across stages of disease. Since 2011, we have leveraged our research platform, including expertise in molecular targeting and world-class drug design capabilities, to rapidly and reproducibly translate science into a broad pipeline of precision therapies. Today, we are delivering our approved medicines, AYVAKIT®/AYVAKYT® (avapritinib) and GAVRETO® (pralsetinib), to patients in the U.S. and Europe, and we are globally advancing multiple programs for systemic mastocytosis (SM), lung cancer and other genomically defined cancers, and cancer immunotherapy.

Our drug discovery approach combines our biological insights with our proprietary compound library and chemistry expertise to design highly selective and potent precision therapies, with the goal of delivering significant and durable clinical benefit to patients based on the genetic driver of their disease. This uniquely targeted, scalable approach is designed to empower the rapid design and development of new treatments and increase the likelihood of success. In addition, our business model integrates our research engine with robust clinical development and commercial capabilities in oncology and hematology to create a cycle of innovation.

Systemic Mastocytosis and other Mast Cell Disorders — AYVAKIT® (avapritinib) and BLU-263

Avapritinib

We are developing and commercializing avapritinib for the treatment of advanced SM and developing avapritinib for the treatment of non-advanced SM. SM is a rare hematologic disorder that causes an overproduction of mast cells and the accumulation of mast cells in the bone marrow and other organs, which can lead to a wide range of debilitating symptoms and, in advanced forms of the disease, organ dysfunction and failure. Nearly all cases of SM are driven by the KIT D816V mutation, which aberrantly activates mast cells.

In June 2021, the FDA approved avapritinib under the brand name AYVAKIT for the treatment of adult patients with advanced SM, including aggressive SM (ASM), SM with an associated hematologic neoplasm (SM-AHN), and mast cell leukemia (MCL). In March 2022, the European Commission expanded the marketing authorization for AYVAKYT to include the treatment of adult patients with ASM, SM-AHN, or MCL, after at least one systemic therapy. We launched AYVAKYT in advanced SM in Germany within one week after receiving the European Commission approval and plan to make AYVAKYT commercially available in other European countries based on local reimbursement and access pathways.

We are also evaluating avapritinib in an ongoing registration-enabling Phase 2 clinical trial in non-advanced SM, which we refer to as our PIONEER trial. In January 2022, we announced that the PIONEER trial was fully enrolled. We plan to report top-line data for Part 2 of the PIONEER trial in late summer 2022 and to submit a supplemental new drug application (sNDA) to the FDA for avapritinib in non-advanced SM in the second half of 2022.

The FDA has granted breakthrough therapy designation to avapritinib for (i) the treatment of advanced SM, including the subtypes of ASM, SM-AHN and MCL, and (ii) the treatment of moderate to severe indolent SM. In addition, the FDA has granted orphan drug designation to avapritinib for the treatment of mastocytosis, and the European Commission has granted orphan medicinal product designation to avapritinib for the treatment of mastocytosis.

BLU-263

We are developing BLU-263, an investigational, orally available, potent and highly selective KIT inhibitor, for the treatment of non-advanced SM and other mast cell disorders. BLU-263 is designed to have equivalent potency as avapritinib, with low off-target activity and lower central nervous system (CNS) penetration relative to avapritinib based on preclinical data, which we believe will enable development of BLU-263 in a broad population of patients with non-advanced SM, including patients with lower disease burden and potentially patients with other mast cell disorders.

In April 2021, we presented results from a Phase 1 trial of BLU-263 in healthy volunteers at the virtual American Association for Cancer Research (AACR) Annual Meeting, which showed that BLU-263 was well-tolerated at all doses tested. Based on these data, we initiated the Phase 2/3 trial of BLU-263 in patients with non-advanced SM, which we refer to as our HARBOR trial, in the second quarter of 2021. We anticipate presenting initial data from the HARBOR trial in the second half of 2022.

RET-altered Cancers — GAVRETO® (pralsetinib)

We are developing and commercializing pralsetinib for the treatment of RET fusion-positive non-small cell lung cancer (NSCLC), and for the treatment of RET-altered thyroid carcinoma, including medullary thyroid cancer (MTC). We are also developing pralsetinib for the treatment of other RET-altered solid tumors. We have granted exclusive licenses to F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (which we refer to together as Roche) and CStone Pharmaceuticals (CStone), to develop and commercialize pralsetinib in their respective territories. See "— Collaborations and Licenses Summary" below.

Pralsetinib received accelerated approval in the U.S. under the brand name GAVRETO for the treatment of (i) adult patients with metastatic RET fusion-positive NSCLC as detected by an FDA approved test, (ii) adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant MTC who require systemic therapy, and (iii) adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

In November 2021, Roche announced that the European Commission granted conditional marketing authorization for GAVRETO as a monotherapy for the treatment of adults with RET fusion-positive advanced NSCLC not previously treated with a RET inhibitor. Roche submitted a Type II variation MAA to the EMA for pralsetinib for RET-altered thyroid cancers in December 2021, as well as marketing applications for pralsetinib for RET-altered NSCLC and thyroid cancers across multiple global geographies in 2021. Marketing applications are planned for pralsetinib for RET-altered NSCLC and thyroid cancers across additional global geographies in 2022.

In March 2021, China's NMPA approved GAVRETO for the treatment of RET fusion-positive NSCLC patients previously treated with platinum-based chemotherapy. In March 2022, China's National Medicinal Products Administration (NMPA) approved GAVRETO for the treatment of RET-mutant MTC and RET fusion-positive thyroid cancer. In February 2022, the Taiwan Food and Drug Administration (TFDA) accepted CStone's NDA for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC, RET-mutant MTC, and RET fusion-positive TC. In March 2022, the Hong Kong Department of accepted CStone's NDA for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC.

We are currently evaluating pralsetinib in an ongoing registration-enabling Phase 1/2 clinical trial in patients with RET-altered NSCLC, MTC and other advanced solid tumors, which we refer to as the ARROW trial. In addition, Roche is conducting multiple ongoing studies, including a registration-enabling Phase 3 clinical trial in treatment-naïve patients with RET fusion-positive NSCLC, which is referred to as the ACCELERET-Lung trial; and a registration-enabling Phase 3 clinical trial in patients with locally advanced or metastatic RET-mutated MTC who have not

previously received a standard of care multi-kinase inhibitor therapy, which is referred to as the ACCELERET-MTC trial. In June 2021, we reported updated data from the ARROW trial in metastatic RET fusion-positive NSCLC and other advanced solid tumors at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting. The ARROW trial was fully enrolled in December 2021. Pursuant to our collaboration with Roche, we are co-developing pralsetinib globally in RET-altered solid tumors, including NSCLC, MTC and other thyroid cancers, as well as other solid tumors.

The FDA has granted breakthrough therapy designation to pralsetinib for (i) the treatment of patients with RET fusion-positive NSCLC that has progressed following platinum-based chemotherapy, and (ii) the treatment of patients with RET mutation-positive MTC that requires systemic treatment and for which there are no acceptable alternative treatments. In addition, the FDA has granted orphan drug designation to pralsetinib for the treatment of RET-rearranged NSCLC, JAK1/2-positive NSCLC or TRKC-positive NSCLC.

PDGFRA-Driven Gastrointestinal Stromal Tumors — AYVAKIT® / AYVAKYT® (avapritinib)

We are commercializing avapritinib for the treatment of patients with PDGFRA exon 18 gastrointestinal stromal tumors (GIST), a rare disease that is a sarcoma, or tumor of bone or connective tissue, of the gastrointestinal tract. Avapritinib is approved in the U.S. under the brand name AYVAKIT for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations, and is approved in Europe with conditional marketing authorization under the brand name AYVAKYT as a monotherapy for the treatment of adult patients with unresectable or metastatic GIST harboring a PDGFRA D842V mutation.

In March 2021, CStone announced that China's NMPA approved AYVAKIT for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. AYVAKIT received accelerated approval in April 2021 from the TFDA and approval in Hong Kong in December 2021, both for adults with unresectable or metastatic GIST harboring PDGFRA D842V mutations.

The FDA has granted breakthrough therapy designation for avapritinib for the treatment of unresectable or metastatic GIST harboring the PDGFRA D842V mutation. In addition, the FDA has granted orphan drug designation to avapritinib for the treatment of GIST, and the European Commission has granted orphan medicinal product designation to avapritinib for the treatment of GIST.

EGFR-Mutated NSCLC — BLU-945, BLU-701 and BLU-451

We are developing three investigational epidermal growth factor receptor (EGFR) inhibitors, BLU-945, BLU-701 and BLU-451, which was formerly known as LNG-451, with the goal of addressing nearly all activating mutations (>90 percent) in EGFR-driven NSCLC; specifically, exon 19 deletions, the L858R mutation, and exon 20 insertions. The introduction of EGFR-targeted therapies, including osimertinib, has transformed the care of patients with EGFR-driven NSCLC. However, there remain significant opportunities to improve outcomes for EGFR-mutant NSCLC patients. First, osimertinib has demonstrated shorter overall survival and progression-free survival in patients with L858R activating mutations. Second, the majority of patients will progress due to the emergence of tumor resistance, including specific EGFR-driven, on target resistance as well as off-target bypass resistance. Third, the brain is a common site of disease progression that has proven difficult to treat. Our portfolio of investigational therapies are designed to address each of these opportunities, alone and in combination with other therapies, with the goal of prolonging patient benefit and preventing the emergence of tumor resistance in the front line, addressing on- and off-target mechanisms of resistance in the second line and later lines of treatment, and preventing and treating brain metastases with enhanced CNS penetration.

BLU-945 and BLU-701 were specifically designed to provide comprehensive coverage of common activating and resistance mutations, spare wild-type EGFR and other kinases to limit off-target toxicities, which is expected to improve the potential combinability with other therapies, and treat or prevent CNS metastases. We believe these profiles may enable BLU-945 and BLU-701 to become the backbones of a range of combination strategies with the potential to address important medical needs for patients with EGFR-driven NSCLC, including in early line treatment settings. We plan to develop BLU-945 and BLU-701 in combination with each other and other therapies, including osimertinib chemotherapy, and antibody drug conjugates, as initial treatments designed to address outstanding unmet needs in patients with activating mutations and prevent both on-target and off-target resistance from emerging. In addition, we plan to develop BLU-945 and BLU-701 as monotherapies and in combination with other therapies in certain biomarker-

selected patient populations in the second line and later lines of treatment. We plan to initiate these combination studies as expansion cohorts in the Phase 1/2 trials in EGFR-mutated NSCLC, which we refer to as our SYMPHONY and HARMONY trials throughout the remainder of 2022 and into 2023, with the goal of generating data to further inform development and registration strategies, including opportunities for expedited approvals. We believe that our comprehensive development plan will allow us to address the unmet needs in EGFR-mutant NSCLC that affect nearly 60,000 patients in major markets, including the US, European Union (EU), the UK, and Japan.

In December 2021, we completed our acquisition of Lengo Therapeutics, Inc., along with its lead compound LNG-451, which we now refer to as BLU-451. BLU-451 is an oral precision therapy in development for the treatment of NSCLC in patients with EGFR exon 20 mutations.

EGFR-Positive NSCLC — BLU-945

BLU-945 is a selective and potent investigational inhibitor of EGFR harboring either the activating L858R or exon 19 deletion mutations combined with the acquired T790M and C797S mutations, the most common on-target resistance mutations to first-generation EGFR inhibitors and osimertinib, respectively. In early data from the ongoing Phase 1 dose escalation part of the SYMPHONY trial presented at the AACR Annual Meeting in April 2022, BLU-945 demonstrated dose-dependent decreases in EGFR variant allele fractions via circulating tumor DNA (ctDNA) analysis, and radiographic tumor reductions including an unconfirmed partial response (PR) observed in a patient treated with 400 mg once daily (QD), the highest dose tested as of the data cutoff date. Pharmacokinetic results showed BLU-945 exposures at higher doses were associated with broad EGFR mutation coverage, including the activating L858R mutation with or without acquired resistance mutations. BLU-945 was generally well-tolerated, with no significant adverse events (AEs) associated with wild-type EGFR inhibition. The maximum tolerated dose and recommended Phase 2 dose have not yet been identified, and dose escalation is continuing. We initiated a BLU-945 and osimertinib combination cohort in the ongoing Phase 1/2 SYMPHONY trial in the second quarter of 2022, with initiation of further combination cohorts planned in the second half of 2022 and in 2023.

EGFR-Positive NSCLC — BLU-701

BLU-701 is a selective and potent investigational inhibitor of EGFR harboring either the activating L858R or exon 19 deletion mutations combined with the acquired C797S mutation. In preclinical data presented at the virtual AACR Annual Meeting in April 2021, BLU-701 showed strong and durable inhibition of tumor growth at doses that are EGFR wild-type sparing, and the potential to be used in both first- and second-line settings. BLU-701 indicated significant CNS penetration in preclinical models, with comparable exposure in the plasma and brain, which illustrates its potential to treat or prevent CNS metastases in patients with EGFR-driven tumors. Based on these preclinical data, in the fourth quarter of 2021, we initiated a Phase 1/2 trial of BLU-701 in EGFR-mutant NSCLC, which we refer to as our HARMONY trial. We plan to present initial clinical data from the HARMONY trial in the second half of 2022.

EGFR-Positive NSCLC – Combinations with BLU-945 and/or BLU-701

Based on their differentiated selectivity profiles and potency against on-target EGFR activating and resistant mutants, we believe BLU-945 and BLU-701 have the potential to become backbone therapies for a range of monotherapy or combination strategies for EGFR-positive NSCLC in the first line and later lines of treatment. These combination strategies include BLU-945 and BLU-701 with osimertinib, chemotherapy, and antibody drug conjugates, as well as BLU-945 and BLU-701 together. Our development plans are driven by BLU-945 and BLU-701 preclinical data which demonstrate coverage of both activating and resistance mutations in EGFRm NSCLC, a broad window over wild-type, and strong CNS penetration. Preclinical data presented at the British Thoracic Oncology Group (BTOG) Annual Conference in January 2022 and the AACR Meeting in April 2022 showed potent antitumor activity on models of exon 19 deletion or LR-driven disease, with or without on-target resistance, supporting the development of both investigational agents in combination in the first- and second-line settings. We plan to initiate these combination studies as expansion cohorts in the ongoing Phase 1/2 SYMPHONY and HARMONY trials during the remainder of 2022 and in 2023.

EGFR Exon 20 Insertion-Positive NSCLC — BLU-451

BLU-451 is a selective and potent investigational inhibitor under development for the treatment of EGFR exon 20 insertion-positive NSCLC. In April 2022, we presented the first preclinical data for BLU-451 at the AACR Annual Meeting demonstrating that BLU-451 is a wild-type EGFR-sparing, CNS penetrant molecule which potently inhibited a broad range of exon 20 insertions and uncommon oncogenic point mutations. In addition, BLU-451 led to measurable tumor regression in a preclinical intracranial tumor model. Based on these foundational preclinical data, in March 2022 we initiated the Phase 1/2 trial of BLU-451 in patients with EGFR-driven NSCLC harboring exon 20 insertion mutations. We plan to present clinical proof-of-concept data for BLU-451 in 2023.

Cyclin E-Aberrant Cancers — BLU-222

We are developing an investigational inhibitor, BLU-222, targeting CDK2 for the treatment of patients with CDK2-vulnerable cancers. CDK2 is cell cycle regulator and an important cancer target, with relevance across multiple malignancies, including estrogen-receptor-positive breast cancer and other CCNE1 amplified tumors. In subsets of patients across multiple cancer types, aberrant CCNE1 hyperactivates CDK2, resulting in cell cycle dysregulation and tumor proliferation. Aberrant CCNE1 has been observed as a primary driver of disease, as well as a mechanism of resistance to CDK4/6 inhibitors and other therapies.

At the AACR Annual Meeting in April 2022, we presented preclinical data showing BLU-222 demonstrated significant antitumor activity in a CCNE1-amplified ovarian cancer model. BLU-222 in combination with standard of care agents, including chemotherapy and the PARP inhibitor olaparib, led to sustained tumor regression even after treatment cessation. In the first quarter of 2022, we initiated the Phase 1/2 trial of BLU-222 in CDK2-vulnerable cancers, which we refer to as our VELA trial. BLU-222 is being developed as monotherapy and in combination with other agents, including CDK4/6 inhibitors and ER antagonists, in hormone-receptor-positive, HER2-negative breast cancer (HR+/HER- BC), and as a single agent and in combination in other CCNE1-amplified tumor types.

Advanced Cancers — BLU-852

BLU-852 is a selective and potent investigational inhibitor of MAP4K1, a well-characterized immunokinase involved in the regulation of immune cells. Preclinical data presented at the virtual AACR Annual Meeting in April 2021 show that MAP4K1 inhibition enhanced intratumoral immune cell activation, overcame Treg mediated T cell suppression, and reduced tumor burden both as a monotherapy and in combination with checkpoint inhibition. These preclinical data support the continued development of BLU-852. Under our ongoing cancer immunotherapy collaboration, we expect Roche to initiate a Phase 1 trial of BLU-852, as a single agent and in combination with atezolizumab, in advanced cancers in 2023.

Discovery Platform

We plan to continue to leverage our discovery platform to systematically and reproducibly identify kinases that are drivers of diseases in genomically defined patient populations, and craft drug candidates that potently and selectively target these kinases. In addition, we plan to expand our discovery platform by building capabilities, supported by external collaborations, for targeted protein degradation of both kinase and non-kinase targets in precision oncology, with the goal of advancing transformative therapies to patients and further broadening the significant productivity of our research engine. Beyond the discovery programs described above, we have multiple pre-development candidate programs for undisclosed kinase targets. In 2022, we plan to nominate two development candidates from our discovery programs. We also plan to share our vision for our expanded discovery platform at an R&D Day in the second half of 2022.

Under our targeted protein degradation collaboration with Proteovant, we plan to research and advance up to two novel protein degrader programs into development, with the option to expand to two additional programs. Under our

immunotherapy collaboration with Roche, we are conducting activities for up to two discovery programs, including BLU-852. See "*—Collaborations and Licenses*" Summary below.

Development and Commercialization Rights

We currently have worldwide development and commercialization rights to avapritinib and fisogatinib, other than the rights licensed to CStone for these drug candidates in Mainland China, Hong Kong, Macau and Taiwan (the CStone territory). We have entered into distribution agreements for certain European countries in which we do not have our own infrastructure, and we plan to pursue additional regulatory approvals and commercialization of avapritinib in additional countries, including through additional distribution agreements.

We have granted Roche an exclusive license to develop and commercialize pralsetinib worldwide, excluding the CStone territory and the U.S., and a co-exclusive license in the U.S. to develop and commercialize pralsetinib. We have granted CStone an exclusive license to develop and commercialize pralsetinib in the CStone territory.

We currently have worldwide development and commercialization rights to BLU-945 and BLU-701, other than the rights licensed to Zai Lab for these drug candidates in Mainland China, Hong Kong, Macau, and Taiwan (collectively, the Zai territory).

Other than the discovery-stage cancer immunotherapy programs (including BLU-852) under our collaboration with Roche, we have worldwide development and commercialization rights to all of our development and discovery programs, including BLU-451, BLU-222, BLU-263.

We have granted an exclusive worldwide license to Clementia Pharmaceuticals, Inc. (Clementia), a wholly-owned subsidiary of Ipsen S.A., to develop and commercialize BLU-782.

Collaborations and Licenses

Roche—Immunotherapy Collaboration. In March 2016, we entered into a collaboration with Roche to discover, develop and commercialize small molecule therapeutics targeting kinases believed to be important in cancer immunotherapy (including the kinase target MAP4K1, which is believed to play a role in T cell regulation), as single products or possibly in combination with other therapeutics.

Roche—Pralsetinib Collaboration. In July 2020, we entered into a collaboration with Roche to develop and commercialize pralsetinib for the treatment of RET-altered cancers. Under the collaboration, we and Genentech are co-commercializing GAVRETO in the U.S., and Roche has exclusive commercialization rights for pralsetinib outside of the U.S., excluding the CStone territory. We and Roche are also co-developing pralsetinib globally in RET-altered solid tumors, including NSCLC, MTC and other thyroid cancers, and expanding development of pralsetinib in multiple treatment settings.

CStone. In June 2018, we entered into a collaboration with CStone to develop and commercialize avapritinib, pralsetinib and fisogatinib, as well as back-up forms and certain other forms, in the CStone territory either as a monotherapy or as part of a combination therapy.

Clementia. In October 2019, we entered into a license agreement with Clementia Pharmaceuticals, Inc. (Clementia), a wholly-owned subsidiary of Ipsen S.A., and granted Clementia an exclusive, worldwide, royalty-bearing license to develop and commercialize BLU-782, as well as specified other compounds related to the BLU-782 program. BLU-782 is an investigational, orally available, potent and highly selective inhibitor that targets mutant ALK2 in development for the treatment of FOP. The FDA has granted a rare pediatric disease designation, orphan drug designation and fast track designation to BLU-782, each for the treatment of FOP. Clementia initiated patient dosing in a Phase 2 clinical trial of BLU-782, now referred to as IPN60130, in the first quarter of 2022.

Zai Lab. In November 2021, we entered into a collaboration with Zai Lab to develop and commercialize BLU-701 and BLU-945 for the treatment of EGFR-driven NSCLC in Greater China, including Mainland China, Hong Kong,

Macau and Taiwan. The collaboration aims to accelerate and expand global development of BLU-701 and BLU-945.

Proteovant. In February 2022, we entered into a collaboration with Proteovant to research and advance novel targeted protein degrader therapies to address medical needs in oncology and hematology. The collaboration will leverage Proteovant's artificial intelligence-enhanced targeted protein degradation platform and our small molecule precision medicine capabilities to discover and advance up to two novel protein degrader target programs into development, with the option to extend to two additional programs.

Mergers & Acquisitions Summary

Lengo Therapeutics. In December 2021, we completed our acquisition of Lengo Therapeutics, Inc., along with its lead compound LNG-451, now known as BLU-451, which is in development for the treatment of NSCLC in patients with EGFR exon 20 insertion mutations. The acquisition also brought additional undisclosed preclinical precision oncology programs and research tools, including a catalog of covalent, highly brain penetrant kinase inhibitors that we plan to add to our proprietary compound library to further enable future drug discovery efforts.

We will continue to evaluate additional collaborations, acquisitions, partnerships and licenses that could maximize the value of our programs and allow us to leverage the expertise of strategic collaborators, partners and licensors, including in additional geographies where we may not have current operations or expertise. We are also focused on engaging in collaborations, acquisitions, partnerships and license agreements to capitalize on or expand our discovery platform.

Note on the Ongoing COVID-19 Pandemic

Due to the continued evolution and uncertain global impacts of the ongoing COVID-19 pandemic, and the ongoing identification of new variants of COVID-19, we cannot precisely determine or quantify the impact this pandemic will have on our business, operations and financial performance. For our ongoing and planned clinical trials, while we anticipate and have experienced some delays or disruptions due to the COVID-19 pandemic, in particular with respect to activation of additional clinical trial sites and patient enrollment rates, we have continued to work with any impacted clinical trial sites to ensure study continuity, enable medical monitoring, facilitate study procedures and maintain clinical data and records, including the use of local laboratories for testing and tumor imaging, home delivery of study drug and remote data and records monitoring. We currently have sufficient supply or plans for supply to meet our anticipated global commercial and clinical development needs for our approved drugs and clinical-stage drug candidates, but we will continue to monitor the impact of the ongoing COVID-19 pandemic on potential disruptions in our current or future supply chain. COVID-19 may also impact and has impacted our commercial activities for AYVAKIT/AYVAKYT and GAVRETO, including patient access to testing and identification, but we have observed an increase in in-person engagements and will continue to conduct commercial and medical affairs field activities across our portfolio in virtual formats where in-person interactions are not feasible. We will continue to assess the duration, scope and severity of the COVID-19 pandemic as it evolves and the existing and potential impacts on our business, operations and financial performance, and we will continue to work closely with our third-party vendors, collaborators and other parties in order to seek to advance our pipeline of targeted therapies as quickly as possible, while keeping the health and safety of our employees and their families, healthcare providers, patients and communities a top priority. Please refer to our Risk Factors in Part II, Item IA of this Quarterly Report on Form 10-Q for further discussion of risks related to the COVID-19 pandemic.

Note on the Conflict in Ukraine

On February 24, 2022, Russian forces invaded Ukraine, which has resulted in conflict and disruption in the region. In response to this action taken by Russia, the U.S. and other countries immediately imposed various economic sanctions against Russia. In the event Russia's invasion continues or geographically expands, additional governmental sanctions may be enacted. The direct and indirect impacts of this evolving situation and its effect on global economies in future periods are difficult to predict. We are monitoring the invasion in Ukraine, the impact in the region, and any broader economic effects from the crisis. To date, the Russian invasion of Ukraine has not had a material impact on our business, operations or financial performance.

Financial Operations Overview

To date, we have financed our operations primarily through public offerings of our common stock, private placements of our convertible preferred and common stock, collaborations and a license agreement. Through March 31, 2022, we have received an aggregate of $3.0 billion from such transactions, including $1.9 billion in aggregate gross proceeds from the sale of common stock in our initial public offering (IPO), follow-on public offerings, through our "at the market" stock offering program and the equity investment by Roche, $115.1 million in gross proceeds from the issuance of convertible preferred stock, $1.0 billion in upfront payments and milestone payments under our collaborations with Roche, CStone and Zai Lab, our license agreement with Clementia and our former collaboration with Alexion Pharma Holding (Alexion). In addition, since January 2020, we have also generated revenue through the sales of our approved drug products.

Since inception, we have incurred significant operating losses, with the exception of the year ended December 31, 2020. Our net loss was $106.0 million for three months ended March 31, 2022. For the year ended December 31, 2021, our net loss was $644.1 million, which included $260.0 million of expenses related to the acquisition of Lengo, and our net income was $313.9 million for the year ended December 31, 2020, primarily due to the collaboration revenue recorded under our collaboration with Roche for pralsetinib. Our net loss was $347.7 million for the year ended December 31, 2019. As of March 31, 2022, we had an accumulated deficit of $1,381.4 million. We expect to continue to incur significant expenses and operating losses over the next few years. We anticipate that our expenses will continue to increase in connection with our ongoing activities, particularly as we:

- maintain and expand our sales, marketing and distribution infrastructure to continue to commercialize our drug and any current or future drug candidates for which we may obtain marketing approval;
- seek marketing approval for our drug candidates, including avapritinib and pralsetinib in additional indications or in additional geographies;
- continue to advance clinical development activities for avapritinib and pralsetinib and initiate or advance clinical development activities for other current or future drug candidates as monotherapies or in combination with other agents;
- continue to discover, validate and develop additional drug candidates or development candidates, including BLU-701, BLU-945, BLU-451, BLU-263 and BLU-222;
- continue to manufacture increasing quantities of drug substance and drug product material for use in preclinical studies, clinical trials and commercialization and to purchase quantities of other agents for use in our clinical trial as we develop our drugs and drug candidates as potential combination therapies or for use as comparator agents;
- conduct development and commercialization activities for companion diagnostic tests for our drugs and drug candidates;
- conduct research and development activities under our collaborations with Roche, CStone, Zai Lab and Proteovant;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license additional businesses, technologies, drugs or drug candidates, form strategic alliances or create joint ventures with third parties; and
- hire additional research, clinical, quality, manufacturing, regulatory, commercial and general and administrative personnel.

Revenue

In January 2020, the FDA granted approval of avapritinib under the brand name AYVAKIT for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. In September 2020, the European Commission granted conditional marketing authorization to AYVAKYT as a monotherapy for the treatment of adult patients with unresectable or metastatic GIST harboring the PDGFRA D842V mutation. In June 2021, the FDA granted a subsequent approval for AYVAKIT, expanding the labeled indications to include adult patients with advanced SM, including aggressive SM, SM with an associated hematological neoplasm and mast cell leukemia. In March 2022, the European Commission expanded the marketing authorization for AYVAKYT to include the treatment of adult patients with ASM, SM-AHN, or MCL, after at least one systemic therapy.

In September 2020, the FDA granted accelerated approval to pralsetinib under the brand name GAVRETO for the treatment of adult patients with metastatic RET fusion-positive NSCLC as detected by an FDA approved test. In December 2020, the FDA granted a subsequent accelerated approval for GAVRETO, expanding the labeled indications to include adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant MTC who require systemic therapy, or with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

For the three months ended March 31, 2022, our revenue primarily consisted of product sales of AYVAKIT/ AYVAKYT as well as collaboration revenue under our collaboration with CStone and license agreement with Clementia. We transferred certain responsibilities associated with product sales to customers, pricing and distribution matters related to U.S. product sales of GAVRETO to Roche on July 1, 2021, and have not recorded any net product revenue from product sales of GAVRETO after this date. For additional information, see Note 9, *Collaboration and License Agreements*, to our unaudited condensed consolidated financial statements. Collaboration revenue for the three months ended March 31, 2022 primarily includes amounts that were recognized related to milestone payments, amounts due to us for supply of inventory (under our collaboration agreements) and research and development services, and royalties on drug sales.

In the future, we expect to generate revenue from a combination of sources, including sales of our current drug product and any current or future drug candidates for which we receive marketing approval, royalties on drug sales, upfront, milestone, profit sharing and other payments, if any, under any current or future collaborations and licenses, including revenues related to the supply of our drug candidates or approved drugs to our various collaboration partners. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of product sales, license fees, research and development services, payments for manufacturing services, and option fees, milestone payments or other payments under our collaboration or license agreements, if any.

Cost of Sales

Our cost of sales includes the cost of producing and distributing inventories that are related to product revenue as well as the sale of drug substance and drug product to our collaboration partners during the respective period, including salary related expenses and stock-based compensation expense for employees involved with production and distribution, freight, and indirect overhead costs. In addition, shipping and handling costs for product shipments are recorded in cost of sales as incurred.

Prior to receiving the initial FDA approval for AYVAKIT and GAVRETO in January 2020 and September 2020, respectively, and subsequent approval for AYVAKIT in June 2021, we manufactured inventory to be sold upon commercialization and recorded approximately $37.7 million related to this inventory as research and development expense. As a result, certain manufacturing costs related to the inventory build-up incurred before FDA approval were expensed in prior periods and are therefore excluded from the cost of goods sold for the three months ended March 31, 2022. We estimate our cost of goods sold related to product revenue as a percentage of net product revenue will continue to be positively impacted as we sell through certain inventory that was previously expensed prior to FDA approval. We expect to utilize low-cost inventory for an extended period of time. Once the low-cost inventory balances are sold through, we estimate our costs of goods sold related to product sales to remain in the mid-single digit percentage

range. Cost of goods sold related to sales of drug products to our collaboration partners are at lower margins and will partially offset the positive impact of the previously expensed inventory.

Expenses

Collaboration Loss Sharing

On July 1, 2021, Roche took over certain responsibilities associated with product sales to customers, pricing and distribution matters related to GAVRETO in the U.S. and became the principal for recording product sales to customers in the U.S. Collaboration loss sharing consists of our share of the losses incurred from sales of GAVRETO to customers in the U.S. under our collaboration for pralsetinib with Roche. For additional information, see Note 9, *Collaboration and License Agreements*, to our unaudited condensed consolidated financial statements. We expect collaboration loss sharing will fluctuate from quarter to quarter as a result of the timing and amount of GAVRETO sales.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research and development activities, including our drug discovery efforts, and the development of our drug candidates, which include:

- expenses incurred to acquire in-process research and development asset with no alternative future use;
- employee-related expenses including salaries, benefits, and stock-based compensation expense;
- expenses incurred under agreements with third parties that conduct research and development, preclinical activities, clinical activities and manufacturing on our behalf;
- expenses incurred under agreements with third parties for the development and commercialization of companion diagnostic tests;
- expenses incurred in connection with research and development activities under our immunotherapy collaboration with Roche, and development activities under our collaboration for pralsetinib with Roche;
- the cost of consultants in connection with our research and development activities;
- the cost associated with regulatory quality assurance and quality control operations;
- the cost of lab supplies and acquiring, developing and manufacturing preclinical study materials, clinical trial materials and commercial supply materials; and
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other operating costs in support of research and development activities.

Research and development costs are expensed as incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

The successful development of our drug candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of these drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of our current or future drug candidates for which we received marketing approval. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- establishing an appropriate safety profile with IND-enabling toxicology studies;
- successful initiation, enrollment in, and completion of clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for AYVAKIT/AYVAKYT, GAVRETO and our drug candidates;
- commercializing AYVAKIT/AYVAKYT, GAVRETO and our drug candidates, if and when approved, whether alone or in collaboration with others;
- market acceptance of AYVAKIT/AYVAKYT, GAVRETO and any future drug we may commercialize; and
- continued acceptable safety profile of the drugs following approval.

A change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs and timing associated with the development of that drug candidate.

Research and development activities are central to our business model. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as our drug candidate development programs progress and as we conduct and continue our clinical trials to evaluate our approved drugs for additional indications. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our approved drugs or drug candidates for which we may receive marketing approval, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

A significant portion of our research and development expenses have been external expenses, which we track on a program-by-program basis following nomination as a development candidate. Our internal research and development expenses are primarily personnel-related expenses, including stock-based compensation expense. Except for internal research and development expenses related to collaboration agreements, we do not track our internal research and development expenses on a program-by-program basis as they are deployed across multiple projects under development.

The following table summarizes our external research and development expenses by program for the three months ended March 31, 2022 and 2021. Other development and pre-development candidate expenses, unallocated expenses and internal research and development expenses have been classified separately.

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Avapritinib external expenses	$ 9,973	$ 15,864
Pralsetinib external expenses	10,956	8,917
BLU-263 external expenses	9,096	3,216
BLU-701/945 external expenses	14,477	10,200
BLU-222 external expenses	6,079	2,543
BLU-451 external expenses	2,135	—
Other development and pre-development candidate expenses and unallocated expenses	18,338	15,299
Internal research and development expenses	32,079	23,671
Total research and development expenses	$ 103,133	$ 79,710

* Pralsetinib external expenses includes reduction for reimbursable expenses under our collaboration for pralsetinib with Roche, and other development and pre-development candidate expenses includes reduction for reimbursable expenses under our other collaboration agreement.

We expect that our research and development expenses will increase in future periods as we expand our operations and incur additional costs in connection with our clinical trials and preparing regulatory filings. These increases will likely include the costs related to the implementation and expansion of clinical trial sites and related patient enrollment, monitoring, program management and manufacturing expenses for active pharmaceutical ingredient (API), drug product and drug substance for current and future clinical trials and commercial inventory. In addition, we expect that our research and development expenses will increase in future periods as we incur additional costs in connection with research and development activities under our immunotherapy collaboration with Roche, development activities under our collaboration for pralsetinib with Roche and development activities for companion diagnostic tests for any current and future drug candidates.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of compensation and benefits, including stock-based compensation, for commercial operations and for personnel in executive, finance, accounting, commercial, business development, information technology, legal and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, commercial development activities, legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

We expect that our selling, general and administrative expenses will continue to increase in the future to support additional research and development activities and commercialization activities, including expanding our sales, marketing and distribution infrastructure to commercialize any drugs for which we may obtain marketing approval for additional indications or in additional geographies and expanding our operations globally. These increases will likely include increased costs related to the hiring of additional personnel, legal, auditing and filing fees and general compliance and consulting expenses, among other expenses. We have incurred and will continue to incur additional costs associated with operating as a public company and expanding the scope of our operations.

Interest Income (Expense), Net

Interest income (expense), net consists primarily of income earned on cash equivalents and marketable securities.

Other Income (Expense), Net

Other income (expense), net consists primarily of foreign currency transaction gains or losses.

Income Tax Expense

Income tax expense consists primarily of federal and foreign income taxes incurred.

Critical Accounting Policies and Estimates

For a description of our critical accounting policies and estimates, please see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Financial Operations Overview—Critical Accounting Policies and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2021. There have been no significant changes to our critical accounting policies and estimates since December 31, 2021.

Results of Operations

Comparison of Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021, together with the changes in those items in dollars and as a percentage:

	Three Months Ended March 31,			
	2022	2021	Dollar Change	% Change
		(in thousands)		
Revenues:				
Product revenue, net	$ 23,841	$ 8,955	$ 14,886	166 %
Collaboration revenue	38,890	12,621	26,269	208
Total revenues	62,731	21,576	41,155	191
Cost and operating expenses:				
Cost of sales	5,079	102	4,977	4,879
Collaboration loss sharing	3,265	—	3,265	100
Research and development	103,133	79,710	23,423	29
Selling, general and administrative	57,058	42,002	15,056	36
Total cost and operating expenses	168,535	121,814	46,721	38
Other income (expense):				
Interest income, net	442	738	(296)	(40)
Other expense, net	(453)	(214)	(239)	(112)
Total other income (loss)	(11)	524	(535)	(102)
Loss before income taxes	(105,815)	(99,714)	(6,101)	(6)
Income tax expense	184	—	184	100
Net loss	$ (105,999)	$ (99,714)	$ (6,285)	(6)%

Product Revenue, Net

Net product revenue increased by $14.9 million from $9.0 million for three months ended March 31, 2021 to $23.8 million for three months ended March 31, 2022.

We started generating revenue from sales of AYVAKIT in the first quarter of 2020 following FDA approval of AYVAKIT for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. In September 2020, the European Commission granted conditional marketing authorization to avapritinib under the brand name AYVAKYT as a monotherapy for the treatment of adult patients with unresectable or metastatic GIST harboring the PDGFRA D842V mutation. In June 2021, the FDA granted a subsequent approval for AYVAKIT, expanding the labeled indications to include adult patients with advanced SM, including aggressive SM, SM with an associated hematological neoplasm and mast cell leukemia. In March 2022, the European Commission expanded the marketing authorization for AYVAKYT to include the treatment of adult patients with ASM, SM-AHN, or MCL, after at least one systemic therapy.

We started generating revenue from sales of GAVRETO in the third quarter of 2020 following the initial FDA approval of GAVRETO. GAVRETO was originally approved for the treatment of adult patients with metastatic RET fusion-positive NSCLC and subsequently approved for adult and pediatric patients 12 years of age and older with advanced or metastatic thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). We transferred certain responsibilities associated with product sales to customers, pricing and distribution matters related to U.S. product sales of GAVRETO to our collaboration partner on July 1, 2021, and have not recorded any net product revenue from product sales of GAVRETO after this date. For additional information, see Note 9, *Collaboration and License Agreements*, to our unaudited condensed consolidated financial statements.

The following table summarizes revenue recognized from sales of AYVAKIT/AYVAKYT and GAVRETO during the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,					
	2022			2021		
	United States	Rest of World	Total	United States	Rest of World	Total
AYVAKIT/AYVAKYT	$ 21,328	$ 2,513	$ 23,841	$ 5,575	$ 1,552	$ 7,127
GAVRETO	—	—	—	1,828	—	1,828
Total product revenue, net	21,328	2,513	23,841	7,403	1,552	8,955

Collaboration Revenue

Collaboration revenue increased by $26.3 million from $12.6 million for the three months ended March 31, 2021 to $38.9 million for the three months ended March 31, 2022. The following table summarizes the revenue recognized from our collaboration and license agreements during the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Clementia license agreement	$ 30,000	$ 40
CStone collaboration	9,212	9,271
Other	(322)	3,310
Total collaboration and license revenue	$ 38,890	$ 12,621

Revenue recognized under our license agreement with Clementia for the three months ended March 31, 2022 consisted of a specified development milestone payment. Revenue recognized under our CStone collaboration for the three months ended March 31, 2022 consisted of $4.0 million in a specified regulatory milestone payment and $5.2 million associated with the manufacturing services related to CStone territory-specific activities and royalties on drug sales.

Revenue recognized under our CStone collaboration for the three months ended March 31, 2021 primarily consisted of $9.0 million in milestone revenue related to regulatory and development milestones that were achieved during the period. Other revenue for the three months ended March 31, 2021 was associated with services related to Roche territory-specific activities under our collaboration with Roche for pralsetinib and amortization of the total $64.5 million of upfront and milestone payments achieved as of such period under our cancer immunotherapy collaboration with Roche.

Cost of Product Sales

Cost of product sales increased by $5.0 million from $0.1 million during the three months ended March 31, 2021 to $5.1 million for the three months ended March 31, 2022 and was related to manufacturing costs associated with our products sales as well as costs associated with the sale of drug product to our collaboration partners.

The following table summarizes the cost of sales by type during the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Cost of product sales	$ 633	$ 102
Cost of collaboration sales	4,446	—
Total cost of sales	$ 5,079	$ 102

The increase in costs of product sales was primarily driven by the lower margin product sales to our collaboration partners. Costs associated with our net product revenue remain at higher margins as certain costs associated with the manufacture of our drugs prior to FDA approval were recorded as research and development expenses and, therefore, were not included in cost of sales during such period.

Collaboration Loss Sharing

Our loss sharing under the collaboration with Roche for pralsetinib was $3.3 million for the three months ended March 31, 2022.

Research and Development Expense

Research and development expense increased by $23.4 million from $79.7 million for the three months ended March 31, 2021 to $103.1 million for the three months ended March 31, 2022. The increase in research and development expense was primarily due to an increase of $8.4 million in personnel-related expenses which includes an increase of $1.1 million in stock-based compensation expense, an increase of $5.6 million in expenses associated with the manufacturing of clinical supply, an increase of approximately $4.0 million in costs related to early discovery and building the platform, and a decrease of $4.1 million in reimbursement from the global development cost sharing arrangement under our collaboration with Roche for pralsetinib.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $15.1 million from $42.0 million for the three months ended March 31, 2021 to $57.1 million for the three months ended March 31, 2022. The increase in selling, general and administrative expense was primarily related to an increase of $9.2 million in personnel-related expenses which includes an increase of $1.6 million in stock-based compensation expense, an increase of $3.6 million in commercial expenses to build our commercial infrastructure for commercialization of AYVAKIT/AYVAKYT and GAVRETO, and $4.1 million in other general expenses to operate the business. The increase in selling, general and administrative expense was partially offset by $1.8 million increase in reimbursement in connection with the commercialization of GAVRETO in the U.S. under our collaboration with Roche for pralsetinib.

Interest Income, Net

Interest income, net, decreased by $0.3 million from $0.7 million for the three months ended March 31, 2021 to $0.4 million for the three months ended March 31, 2022.

Other Expense, Net

Other expense, net, increased by $0.2 million from $0.2 million for the three months ended March 31, 2021 to $0.4 million for the three months ended March 31, 2022.

Income Tax Expense

Income tax expense consisted of $0.2 million for the three months ended March 31, 2022, related to withholding income tax incurred related to collaboration revenue generated in a foreign country and international tax provision.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily through public offerings of our common stock, private placements of our convertible preferred and common stock, collaborations and a license agreement. Through March 31, 2022, we have received an aggregate of $3.0 billion from such transactions, including $1.9 billion in aggregate gross proceeds from the sale of common stock in our IPO, follow-on public offerings, through our "at the market" stock offering program and the equity investment by Roche, $115.1 million in gross proceeds from the issuance of convertible preferred stock, $1.0 billion in upfront payments and milestone payments under our collaborations with Roche, CStone and Zai Lab our license agreement with Clementia and our former collaboration with Alexion. In addition, since January 2020, we have also generated revenue through the sales of our approved drug products.

As of March 31, 2022, we had cash, cash equivalents and marketable securities of $893.4 million.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
(in thousands)	**2022**	**2021**
Net cash used in operating activities	$ (132,726)	$ (125,778)
Net cash provided by (used in) investing activities	(41,090)	132,197
Net cash provided by financing activities	1,264	7,011
Net increase (decrease) in cash and cash equivalents	$ (172,552)	$ 13,430

Net Cash Used in Operating Activities. For the three months ended March 31, 2022, compared to the same period in 2021, the $6.9 million increase in net cash used in operating activities was primarily due to a $6.3 million increase in the net loss.

Net Cash Provided by (Used in) Investing Activities. For the three months ended March 31, 2022, compared to the same period in 2021, the $173.3 million decrease in net cash provided by investing activities was primarily due to a $172.3 million decrease in net purchases and maturities of available for sale investments.

Net Cash Provided by Financing Activities. For the three months ended March 31, 2022, compared to the same period in 2021, the $5.7 million decrease in net cash provided by financing activities was primarily due to a $5.7 million decrease in net proceeds received from stock option exercises and employee stock purchase plan.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate or continue clinical trials of, and seek marketing approval for our drug candidates, including marketing approval for avapritinib and pralsetinib for additional indications or avapritinib in additional geographies, to the extent these expenses are not the responsibility of our collaborators. In addition, we expect to incur additional significant commercialization expenses for AYVAKIT/AYVAKYT, GAVRETO and other drug candidates, if approved, related to drug sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of potential collaborators or licensors. We will also incur additional significant costs if we choose to pursue additional indications or geographies for any of our approved drugs or

drug candidates or otherwise expand more rapidly than we presently anticipate. Accordingly, we may seek to obtain additional funding from time to time in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate certain of our research and development programs or future commercialization efforts.

As of March 31, 2022, we had cash, cash equivalents and marketable securities of $893.4 million. Based on our current operating plans, we anticipate our existing cash, cash equivalents and marketable securities, together with anticipated future product revenues, will provide sufficient capital to enable us to achieve a self-sustainable financial profile.

Our future capital requirements will depend on many factors, including:

- the success of our commercialization efforts and market acceptance for AYVAKIT/AYVAKYT, GAVRETO or any of our current or future drug candidates for which we receive marketing approval;
- the costs of maintaining, expanding or contracting for sales, marketing and distribution capabilities in connection with commercialization of AYVAKIT/AYVAKYT and any of our current or future drug candidates for which we receive marketing approval;
- the costs of securing manufacturing, packaging and labeling arrangements for development activities and commercial production, including API, drug substance and drug product material for use in preclinical studies, clinical trials, our compassionate use program and for use as commercial supply, as applicable;
- the cost of purchasing quantities of agents for use in our clinical trials in connection with our efforts to develop our drugs and drug candidates, including for development as combination therapies;
- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our approved drugs and drug candidates;
- the costs, timing and outcome of regulatory review of marketing applications for our drug candidates, including seeking marketing approval for avapritinib and pralsetinib for additional indications or avapritinib in additional geographies;
- the success of our collaborations with Roche, CStone, Zai Lab and Proteovant and our license agreement with Clementia, as well as our ability to establish and maintain additional collaborations, partnerships or licenses on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under our existing collaboration or license agreements, or any collaboration, partnership or license agreements that we may enter into in the future;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, research and development, clinical or other costs under future collaboration agreements, if any;
- the extent to which we acquire or in-license other approved drugs, drug candidates or technologies and the terms of any such arrangements;
- the success of our current or future collaborations for the development and commercialization of companion diagnostic tests;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the costs of continuing to expand our operations.

Identifying potential drug candidates, conducting preclinical development and testing and clinical trials and, for any drug candidates that receive marketing approval, establishing and maintaining commercial infrastructure is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain additional marketing approvals, including for avapritinib and pralsetinib in additional indications or avapritinib in additional geographies, and achieve substantial revenues for any of our drugs that receive marketing approval, including for AYVAKIT/AYVAKYT and GAVRETO. In addition, our drugs and any current or future drug candidates that receive marketing approvals, including avapritinib and pralsetinib for additional indications or avapritinib in additional geographies, may not achieve commercial success. Accordingly, we may need to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial drug revenues, we expect to finance our cash needs primarily through a combination of public and private equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds, other than our collaborations with Roche, CStone and Zai Lab and the license agreement with Clementia, which are limited in scope and duration and subject to the achievement of milestones or royalties on sales of licensed products, if any. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common stockholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs, drugs or drug candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market drug and drug candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases and unconditional purchase obligations related to certain commercial manufacturing agreements.

During the three months ended March 31, 2022, there were no material changes to our contractual obligations and commitments described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the Annual Report on Form 10-K for the year ended December 31, 2021.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of March 31, 2022 and December 31, 2021, we had cash, cash equivalents and marketable securities of $893.4 million and $1,034.6 million, respectively, consisting primarily of money market funds and investments in U.S. government agency and treasury obligations.

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates resulting from the Federal Reserve’s raising of interest rates as well as the Russian invasion of Ukraine. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we believe an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio. We have the ability to hold our investments until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investment portfolio.

We are also exposed to market risk related to changes in foreign currency exchange rates, including recent changes resulting from the Russian invasion of Ukraine. From time to time, we contract with vendors that are located in Asia and Europe, which are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign currency exchange rate risk. As of

March 31, 2022 and December 31, 2021, we held limited funds and future obligations denominated in foreign currencies.

Inflation generally affects us by increasing our cost of labor, clinical trial and manufacturing costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2022 and 2021.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fiscal quarter covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see the Section titled "Forward-Looking Statements" of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risk Factor Summary

Below is a summary of the material risks to our business, operations and the investment in our common stock. This summary does not address all of the risks that we face. Risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q in its entirety before making investment decisions regarding our common stock.

- We have limited experience as a commercial company and the marketing and sale of AYVAKIT® (avapritinib) (marketed in Europe under the brand name AYVAKYT®), GAVRETO® (pralsetinib) or any future approved drugs may be unsuccessful or less successful than anticipated.
- The commercial success of our current and future drugs will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.
- If we are unable to establish additional commercial capabilities and infrastructure, we may be unable to generate sufficient revenue to sustain our business.
- If the market opportunities for our approved drugs or drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected.
- We face substantial competition, which may result in others commercializing, developing or discovering drugs before or more successfully than we do.
- Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any of our approved drugs or drug candidates that we may develop.
- If we are unable to advance our drug candidates to clinical development, develop our drug candidates as monotherapies or in combination with other agents, obtain regulatory approval for our drug candidates, including for avapritinib and pralsetinib for additional indications or in additional geographies, and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our drug candidates and, if applicable, for any related companion diagnostic tests, we will not be able to commercialize, or may be delayed in commercializing, such drug candidates, and our ability to generate revenue will be materially impaired.

- Our drugs and drug candidates may cause undesirable side effects that could delay or prevent their clinical development or regulatory approval, limit the commercial profile of an approved label, result in restrictive distribution or result in significant negative consequences following marketing approval, if any.

- We may not be successful in our efforts to expand our pipeline of drug candidates.

- We are required to comply with comprehensive and ongoing regulatory requirements for any of our current or future approved drugs, including conducting confirmatory clinical trials for any drug that receives accelerated approval. In addition, our current or future approved drugs could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drugs.

- We are a precision therapy company with a limited operating history. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

- We have entered into collaborations and licenses with our partners for the development and commercialization of several of our drugs and drug candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these drugs and drug candidates.

- We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

- We contract with third parties for the manufacture of our approved drugs and drug candidates, including for preclinical, clinical and commercial supply. This reliance on third parties increases the risk that we will not have sufficient quantities of our approved drugs or drug candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

- If we are unable to adequately protect our proprietary technology or obtain and maintain patent protection for our technology and drugs or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

- Our business, results of operations and future growth prospects could be materially and adversely affected by the ongoing COVID-19 pandemic.

- We may acquire or in-license businesses, technologies or platforms, approved drugs, drug candidates or discovery-stage programs, or form strategic alliances, collaborations or partnerships, in the future, and we may not realize the benefits of such acquisitions, in-licenses, alliances, collaborations or partnerships.

- The price of our common stock has been and may in the future be volatile and fluctuate substantially.

Risks Related to Commercialization

We have limited experience as a commercial company and the marketing and sale of AYVAKIT/AYVAKYT, GAVRETO or any future approved drugs may be unsuccessful or less successful than anticipated.

We have two approved precision therapies, AYVAKIT/AYVAKYT and GAVRETO. While we have been commercializing AYVAKIT and GAVRETO in the U.S. and AYVAKYT in Europe, we have limited experience as a commercial company, and there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. Marketing applications for avapritinib and pralsetinib are currently under review or planned in the U.S. or globally. To execute our business plan, in addition to successfully marketing and selling our approved drugs, we will need to successfully:

- establish and maintain our relationships with healthcare providers who will be treating patients who may receive our drugs and any future drugs;
- obtain and maintain adequate pricing and reimbursement for AYVAKIT/AYVAKYT, GAVRETO and any future drugs;
- gain regulatory acceptance for the development and commercialization of current or future drug candidates in our pipeline, including for additional indications or in additional geographies for marketed drugs in our portfolio;
- maintain our existing collaborations with Roche, CStone Pharmaceuticals and Zai Lab;
- expand our global operations or enter into collaboration, partnerships or distribution arrangements in geographies where we may not have current operations or expertise; and
- manage our spending as costs and expenses increase due to clinical trials, marketing approvals, and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully commercialize our current or future approved drugs, develop current or future drug candidates, expand our business or continue our operations.

The commercial success of AYVAKIT/AYVAKYT and GAVRETO, as well as any other drugs that we may bring to the market, will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

AYVAKIT/AYVAKYT and GAVRETO, as well any other drugs that we may bring to the market, may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. If these drugs do not achieve an adequate level of acceptance, we may not generate significant product revenues and may not become profitable. The degree of market acceptance for AYVAKIT/AYVAKYT and GAVRETO, as well as any current or future drug candidates for which we receive marketing approval, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in the drug's approved labeling;
- the relative convenience and ease of administration;
- the willingness of eligible patients to try new therapies and of physicians to prescribe these therapies;

- the length of time that patients who are prescribed our drugs remain on treatment;
- the pricing of our drugs and any current or future drug candidates for which we receive marketing approval;
- publicity concerning our current and future drugs, or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement.

Even if a drug candidate displays a favorable efficacy and safety profile in preclinical and clinical studies and the drug candidate receives marketing approval, market acceptance of the drug will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of our drugs may require significant resources, including more resources than those required for treatments marketed by competitors, and may never be successful. Any of these factors may cause our approved drugs, as well as any current or future drug candidates for which we receive marketing approval, to be unsuccessful or less successful than anticipated.

If we are unable to establish additional commercial capabilities and infrastructure, we may be unable to generate sufficient revenue to sustain our business.

We are continuing to build out our commercial capabilities and infrastructure and have limited sales and distribution experience and limited capabilities for marketing and market access. To successfully commercialize our approved drugs or any current or future drug candidates for which we receive marketing approval, we will need to develop these capabilities and further expand our infrastructure to support commercial operations in the U.S., Europe and other regions, either on our own or with others. We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third party to perform these functions, including marketing and sales functions, we may be unable to compete successfully against these more established companies.

We cannot be sure that we will be able to or can successfully compete with other companies to recruit, hire and retain a sufficient number of sales representatives or that they will be effective at promoting our drugs. In addition, we will need to commit significant additional management and other resources to maintain and grow our sales organization. We may not be able to achieve the necessary development and growth in a cost-effective manner or realize a positive return on our investment.

Factors that may inhibit our efforts to commercialize our drugs include:

- our inability to recruit, train and retain adequate numbers of sales and marketing personnel;
- the inability of sales personnel to obtain access to or to persuade adequate numbers of physicians to prescribe our drugs;
- unforeseen costs and expenses associated with maintaining an independent sales and marketing organization; and
- delays or disruptions to sales and marketing activities, including due to the ongoing COVID-19 pandemic.

In the event that we are unable to effectively deploy our sales organization or distribution strategy on a timely and efficient basis, if at all, the commercialization of our drugs could be delayed which would negatively impact our ability to generate product revenues.

If the market opportunities for our approved drugs or drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected.

The precise incidence and/or prevalence for SM, RET-altered cancers, EGFR-mutated NSCLC, CCNE aberrant cancers and GIST are unknown. Our projections of the number of people who have these diseases, the frequency of the genetic alterations targeted by our drugs and drug candidates and the subset of patients who have the potential to benefit from our treatment options are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or third-party market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our approved drugs and drug candidates may be limited or may not be amenable to treatment with our precision therapies.

Accordingly, the number of patients in the U.S., France, Germany, Italy, Spain, the United Kingdom (UK) and Japan, which we collectively refer to as the Major Markets, and elsewhere, including the number of addressable patients in those markets, may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, patients treated with our drugs and drug candidates may develop mutations that confer resistance to treatment or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

We face substantial competition, which may result in others commercializing, developing or discovering drugs before or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face competition with respect to our drugs and current clinical-stage drug candidates, and we will face competition with respect to any drugs and drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of therapies in the field of kinase inhibition for cancer and other diseases. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies.

AYVAKIT/AYVAKYT faces competition for advanced SM from Novartis AG's midostaurin and imatinib, and may face competition from drug candidates in development, including that being developed by Cogent Biosciences, Inc. If avapritinib and BLU-263 are approved for non-advanced SM, they may face competition from drug candidates in development, including those being developed by AB Science S.A., Allakos Inc. and Cogent Biosciences, Inc.

GAVRETO faces competition for RET fusion-positive NSCLC and RET-altered thyroid carcinoma, including MTC, from Eli Lilly and Company's selpercatinib. If pralsetinib receives marketing approval for patients with other solid tumors, it will likely also face competition from selpercatinib for these additional indications. In addition, pralsetinib may face competition from other drug candidates in development for RET-altered cancers, including those being developed by AstraZeneca plc, Boston Pharmaceuticals, Inc., Eisai Inc., Exelixis, Inc., GlaxoSmithKline plc, Mirati Therapeutics, Inc., Novartis AG, Pfizer Inc., Stemline Therapeutics, Inc., and Turning Point Therapeutics, Inc., as well as several approved multi-kinase inhibitors with RET activity being evaluated in clinical trials, including alectinib, apatinib, cabozantinib, dovitinib, lenvatinib, sorafenib, sunitinib and vandetinib. Pralsetinib's commercial potential may also face indirect competition from chemotherapeutic agents and immuno-oncology products, including those developed by AstraZeneca PLC, Bristol-Myers Squibb Company, EMD Serono & Pfizer Inc., Merck & Co., and Regeneron Pharmaceuticals, Inc.

AYVAKIT/AYVAKYT may face competition from drug candidates in development for PDGFRA-driven GIST, including those being developed by AB Science S.A., ARIAD Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, AROG Pharmaceuticals, Inc., AstraZeneca plc, Celldex Therapeutics, Inc.,

Cogent Biosciences, Inc., Deciphera Pharmaceuticals, LLC, Exelixis, Inc., Ningbo Tai Kang Medical Technology Co. Ltd. and Xencor, Inc.

We are developing BLU-701 and BLU-945 for treatment-resistant EGFR-mutated NSCLC, which, if approved, will face competition from AstraZeneca plc's osimertinib and aumolertinib, which is under collaboration between Jiangsu Hansoh Pharmaceutical Group Co., Ltd. and EQRX, Inc. and approved in China. In addition, BLU-701 and BLU-945 may face competition from drug candidates in development for EGFR-mutated NSCLC, including those being developed by Allist Pharmaceuticals, Arrivent Biopharma, Inc., Betta Pharmaceuticals, Black Diamond Therapeutics, Inc., Boehringer Ingelheim RCV GmbH & Co KG, Bridge Biotherapeutics, Inc., C4 Therapeutics, Inc., Daiichi Sankyo Company, Limited, Janssen Pharmaceuticals, Inc., Kanaph Therapeutics, Theseus Pharmaceuticals, Inc., RedCloud Bio, ERASCA. BLU-701 and BLU-945 may also face indirect competition from chemotherapeutic agents and immuno-oncology products, including those developed by AstraZeneca PLC, Bristol-Myers Squibb Company, EMD Serono & Pfizer Inc., Merck & Co., and Regeneron Pharmaceuticals, Inc.

We are developing BLU-451 for EGFR exon 20 insertion-positive NSCLC, which, if approved, will face competition from Janssen Pharmaceuticals, Inc. and Takeda Pharmaceuticals. In addition, BLU-451 may face competition from drug candidates in development for EGFR exon 20 insertion-positive NSCLC, including those being developed by Abbisko Therapeutics Co., Ltd., Cullinan Oncology, Inc., Dizal Pharmaceutical Co. Ltd., Shenzhen Forward Pharmaceutical Co., Ltd., Shanghai Junshi Biosciences Co., Ltd., Oric Pharmaceuticals, Inc., and Scorpion Therapeutics, Inc. BLU-451 may also face indirect competition from chemotherapeutic agents and immuno-oncology products, including those developed by AstraZeneca PLC, Bristol-Myers Squibb Company, EMD Serono & Pfizer Inc., Merck & Co., and Regeneron Pharmaceuticals, Inc.

We are developing BLU-222 for cyclin E aberrant cancers, which, if approved, will face competition from indication-specific therapies such as Genentech's bevacizumab, AstraZeneca and Merck's olaparib, Clovis Oncology's rucaparib, GSK's niraparib, Merck's pembrolizumab, and Eisai's lenvatinib. In addition, BLU-222 may face competition from drug candidates in development for cyclin E aberrant cancers, including those being developed by Allorian Therapeutics, Inc., ARC Therapeutics, Inc., Cedilla Therapeutics, Inc., Cyclacel Pharmaceuticals Inc., Debiopharm Group, Incyte Corporation, Monte Rosa Therapeutics, Inc., Nuvation Bio, Inc., Regor Therapeutics Inc., Schrodinger, Inc., Simcere Pharmaceutical, Pfizer Inc., AstraZeneca plc, Zentalis Pharmaceuticals, Inc. and Repare Therapeutics, Inc.

We are developing BLU-852 for advanced cancers susceptible to MAP4K1 inhibition, which, if approved, will face competition from immuno-oncology products, including those developed by Bristol-Myers Squibb Company, Merck & Co., Inc., Regeneron Pharmaceuticals, Inc., Sanofi S.A., and AstraZeneca plc. In addition, BLU-852 may face competition from drug candidates in development for advanced cancers susceptible to MAP4K1 inhibition, including those being developed by Treadwell Therapeutics, Inc., BeiGene Ltd., Nimbus Therapeutics, LLC, MingMed Biotechnology Co., Ltd., and Pfizer Inc.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of any related companion diagnostic tests, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any of our approved drugs or drug candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing of our approved drugs and drug candidates in human clinical trials and use of our drug candidates through compassionate use programs, and an even greater risk in connection with our commercialization of our current and future drugs. If we cannot successfully defend ourselves against claims that any of our approved drugs or drug candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any of our approved drugs or drug candidates that we may develop and commercialize;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any of approved drugs or drug candidates that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we may need to further increase our insurance coverage as we begin additional clinical trials or if we successfully commercialize additional drug candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Increasing demand for compassionate use of our drug candidates could negatively affect our reputation and harm our business.

We are developing drug candidates for the treatment of indications for which there are currently limited or no available therapeutic options. It is possible for individuals or groups to target companies with disruptive social media campaigns related to a request for access to unapproved drugs for patients with significant unmet medical need. If we experience a similar social media campaign regarding our decision to provide or not provide access to any of our current or future drug candidates under an expanded access policy, our reputation may be negatively affected and our business may be harmed.

Media attention to individual patients' expanded access requests has resulted in the introduction and enactment of legislation at the local and national level referred to as "Right to Try" laws, such as the federal Right to Try Act of 2017, which are intended to allow patients access to unapproved therapies earlier than traditional expanded access programs. A possible consequence of both activism and legislation in this area may be the need for us to initiate an unanticipated expanded access program or to make our drug candidates more widely available sooner than anticipated.

In addition, some patients who receive access to drugs prior to their commercial approval through compassionate use, expanded access programs or right to try access, collectively referred to as compassionate use programs, have life-threatening illnesses and have exhausted all other available therapies. The risk for serious adverse events in this patient population is high, which, if those adverse events are determined to be drug-related, could have a negative impact on the safety profile of our drug candidates if we were to provide them to these patients, which could cause significant delays or an inability to successfully commercialize our drug candidates and materially harm our business. If we were to provide patients with any of our drug candidates under a compassionate use program, our supply capabilities may limit the number of patients who are able to enroll in the program and we may in the future need to restructure or pause any compassionate use program in order to enroll sufficient numbers of patients in our controlled

clinical trials required for regulatory approval and successful commercialization of our drug candidates, which could prompt adverse publicity or other disruptions related to current or potential participants in such programs.

If we or our collaborators are unable to successfully develop and commercialize companion diagnostic tests for our drugs and drug candidates, or experience significant delays in doing so we may not realize the full commercial potential of our drugs and drug candidates.

Because we are focused on precision medicine, in which predictive biomarkers will be used to identify the right patients for our drugs and drug candidates, we believe that our success may depend, in part, on the development and commercialization of companion diagnostic tests. There has been limited success to date industrywide in developing and commercializing these types of companion diagnostic tests. To be successful, we need to address a number of scientific, technical and logistical challenges. We have entered into agreements to develop and/or commercialize companion diagnostic tests with third parties, including for avapritinib in order to identify GIST patients with the PDGFRA D842V mutation, and pralsetinib in order to identify NSCLC patients with RET fusions and MTC patients with RET mutations. We have limited experience in the development and commercialization of companion diagnostic tests with third parties and may not be successful in developing and commercializing appropriate companion diagnostic tests with third parties to pair with our approved drugs or drug candidates that receive marketing approval. In addition, current commercially available diagnostic tests may become unavailable in the future. Companion diagnostic tests are subject to regulation by the FDA and similar regulatory authorities outside the U.S. as medical devices and require separate regulatory clearance or approval prior to commercialization. We are relying on third parties to design, manufacture, obtain regulatory clearance or approval for and commercialize the companion diagnostic tests, including for avapritinib and pralsetinib, and we expect to rely in whole or in part on third parties to design, manufacture, obtain regulatory clearance or approval for and commercialize any other companion diagnostic tests for current and future drug candidates. We and our collaborators may encounter difficulties in developing and obtaining clearance or approval for the companion diagnostic tests, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. In addition, our collaborators for any companion diagnostic test that we may seek to develop:

- may not perform their respective obligations as expected or as required under our agreements with them;
- may not pursue commercialization of a companion diagnostic test even if it receives any required regulatory clearances or approvals;
- may elect not to continue the development of a companion diagnostic test based on changes in their or other third parties' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- may not commit sufficient resources to the marketing and distribution of a companion diagnostic test; and
- may terminate their relationship with us.

Any delay or failure by us or our collaborators to develop or obtain regulatory clearance or approval of the companion diagnostic tests could delay, prevent or revoke approval of our drug candidates. If we, or any third parties that we have engaged or may in the future engage to assist us are unable to successfully develop and commercialize companion diagnostic tests for our drugs and drug candidates, or experience delays in doing so:

- the development of our approved drugs and drug candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- our drug candidates may not receive marketing approval if safe and effective use of a therapeutic drug candidate depends on an in vitro diagnostic;
- regulatory authorities may impose post-marketing requirements regarding the development and commercialization of companion diagnostic tests for our drugs and drug candidates; and

- we may not realize the full commercial potential of any of our approved drugs or drug candidates that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from treatment with our drugs.

As a result, our business may be materially harmed.

In addition, third party collaborators may encounter production difficulties that could constrain the supply of the companion diagnostic tests, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostic tests in the clinical community. If such companion diagnostic tests fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our current and future drugs. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our approved drugs and drug candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our drugs and drug candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our drugs and drug candidates.

Our reliance on single-source third-party suppliers could harm our ability to commercialize our drugs or any drug candidates that may be approved in the future.

We do not currently own or operate manufacturing facilities for the production of our drugs or any drug candidates that may be approved in the future. We primarily rely on single-source third-party suppliers to manufacture and supply our drugs, which may not be able to produce sufficient inventory to meet commercial demand in a timely manner, or at all. Our third-party suppliers may not be required to provide us with any guaranteed minimum production levels or have dedicated capacity for our drugs. As a result, there can be no assurances that we will be able to obtain sufficient quantities of our drugs or any other drug candidates that may be approved in the future, which could have a material adverse effect on our business as a whole.

If, in the future, we are unable to maintain sales and marketing capabilities or enter into agreements with third parties to sell and market our drugs and drug candidates, we may not be successful in commercializing our drugs and drug candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any drug launch. If the commercial launch of a drug candidate for which we establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, which may be costly.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any current or future drugs ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drugs effectively. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current and future drugs or may be unable to do so on terms that are favorable to us.

If we do not establish and maintain sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drugs and drug candidates, if approved. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

Risks Related to Drug Development and Regulatory Approval

If we are unable to advance our drug candidates to clinical development, obtain regulatory approval for our drug candidates, including for avapritinib and pralsetinib in additional indications or in additional geographies, and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed.

Our ability to generate substantial drug revenues, if ever, will depend heavily on the successful development and commercialization of our drugs and drug candidates. Each of our drug candidates will require additional preclinical or clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, substantial investment and significant marketing efforts before we generate substantial revenues from sales for those drug candidates, if approved. In addition, for some of our drug candidates, in order to select patients most likely to respond to treatment and rapidly confirm mechanistic and clinical proof-of-concept, or to identify appropriate patients for our drugs or drug candidates for which we obtain approval, we may be required or we may seek to develop companion diagnostic tests, which are assays or tests to identify an appropriate patient population. Companion diagnostic tests are subject to regulation as medical devices and must themselves be cleared or approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our drug candidates. The success of our approved drugs and drug candidates will depend on several factors, including the following:

- successful enrollment in, and initiation and completion of, clinical trials, including our ongoing and planned clinical trials for our drugs and drug candidates as monotherapies and in combination with other agents;
- successful initiation and completion of preclinical studies for our other drug candidates;
- successful development of any companion diagnostic tests for use with our drugs and drug candidates;
- receipt of regulatory approvals from applicable regulatory authorities and transitioning any conditional marketing authorizations to full approvals;
- in-house commercial manufacturing capabilities or arrangements with third-parties for clinical supply and commercial manufacturing, packaging and labeling and the receipt by such third-party manufacturers of requisite approvals to supply commercial inventories of our approved drugs and drug candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our drugs and drug candidates;
- successful commercialization of our approved drugs and drug candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our approved drugs and drug candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety profile of our drugs and drug candidates following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drugs and drug candidates, which would materially harm our

business. If we do not receive regulatory approvals for our drug candidates, we may not be able to continue our operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates, including avapritinib and pralsetinib for additional indications, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. Because the target patient populations for our drug candidates and approved drugs in clinical development for additional indications are relatively small, it may be difficult to successfully identify patients. Although we have entered into or plan to enter into agreements with third parties to develop companion diagnostic tests for use in some of our other current or future clinical trials in order to help identify eligible patients, we may experience delays in reaching, or fail to reach, agreement on acceptable terms to develop such companion diagnostic tests. Any third parties whom we engage to develop companion diagnostic tests may experience delays or may not be successful in developing such companion diagnostic tests, furthering the difficulty in identifying patients for our clinical trials. In addition, current commercially available diagnostic tests to identify appropriate patients for our clinical trials or any approved drug candidates may become unavailable in the future.

In addition, we have experienced some delays or disruptions in enrollment in our ongoing clinical trials due to the COVID-19 pandemic, and we anticipate we may experience additional delays or disruptions in the future due to the ongoing COVID-19 pandemic and changes in local site or IRB policies availabilities of site staff reprioritization of hospital resources, restricted access to healthcare professionals and testing sites and other containment measures or concerns among patients about participating in clinical trials during a pandemic. Furthermore, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates and approved drugs in clinical development for additional indications, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates.

Patient enrollment may be affected by other factors including:

- the severity of the disease under investigation;
- the size of the target patient population;
- the eligibility criteria for the clinical trial;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the drug candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to identify patients appropriate for enrollment in our clinical trials, or to enroll a sufficient number of patients in our clinical trials, would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we are unable to include patients with the driver of the disease, including the applicable genomic alteration for diseases in genomically defined patient populations, this could compromise our ability to seek participation in the FDA's

expedited review and approval programs, including breakthrough therapy designation and fast track designation, or otherwise to seek to accelerate clinical development and regulatory timelines.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our drug candidates and, if applicable, for any related companion diagnostic tests, we will not be able to commercialize, or may be delayed in commercializing, such drug candidates, and our ability to generate revenue will be materially impaired.

Our drug candidates and any companion diagnostic tests related to our approved drugs or drug candidates, including the companion diagnostic tests that we are developing or have developed for avapritinib in order to identify GIST patients with the PDGFRA D842V mutation, and pralsetinib in order to identify NSCLC patients with RET fusions and MTC patients with RET mutations, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Before we can commercialize any of our drug candidates, we must obtain marketing approval. We may also need marketing clearance or approval for any related companion diagnostic tests, including the companion diagnostic tests that we are developing for avapritinib and pralsetinib.

We expect to rely on third-party CROs and/or regulatory consultants to assist us in filing and supporting the applications necessary to gain regulatory approvals. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Should FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Our drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, if approval is obtained at all, both in the U.S. and abroad is expensive, may take many years if additional clinical trials are required and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the drug candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA for a drug candidate, pre-market approval (PMA) application for a companion diagnostic test or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. We currently have multiple marketing applications for our drug candidates under review across the world.

Our drug candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication or a related companion diagnostic test is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- delays or disruptions impacting the FDA or comparable foreign regulatory authorities due to the ongoing COVID-19 pandemic.

As of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. On July 16, 2020, FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In addition, even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs and related companion diagnostic tests, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing requirements, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our drug candidates and companion diagnostic tests related to our approved drugs and drug candidates, the commercial prospects for our approved drugs or drug candidates may be harmed and our ability to generate revenues will be materially impaired.

Results from earlier stage trials may not be predictive of the results of later stage trials and interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted and as the data are subject to audit and verification procedures that could result in material changes in the final data.

The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or emergence of unacceptable safety issues, notwithstanding promising results in earlier trials. Most drug candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of any of our drug candidates. Drug candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical studies or clinical trials may show the drug candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- failure to receive the necessary regulatory approvals;
- manufacturing issues, formulation issues, pricing or reimbursement issues or other factors that make a drug candidate uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent one of our drug candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

Additionally, from time to time, we may publish interim or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Material adverse changes between preliminary or interim data and final data could significantly harm our business prospects.

Our drugs and drug candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, result in restrictive distribution or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by any of our approved drugs or drug candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. As is the case with all oncology drugs, it is likely that there may be side effects associated with the use of our drugs and drug candidates. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our drugs or drug candidates for any or all targeted indications. The drug related side effects could affect patient recruitment or the ability of enrolled patients to complete clinical trials or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, our approved drugs and drug candidates could cause undesirable side effects in preclinical studies or clinical trials related to on target toxicity. If on target toxicity is observed, or if our drugs or drug candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our drugs or drug candidates may only be uncovered with a significantly larger number of patients exposed to the drugs or drug candidate. If we or others identify undesirable side effects caused by any of our approved drugs or drug candidates (or any other similar drugs) after marketing approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such drug;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such drug is distributed or administered, conduct additional clinical trials or change the labeling of such drug;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy (REMS) plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such drug from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our drugs and drug candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected drugs or drug candidates and could substantially increase the costs of commercializing our approved drugs and drug candidates, if approved, and significantly impact our ability to successfully commercialize our approved drugs and drug candidates and generate revenues.

A breakthrough therapy designation by the FDA for our drug candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our drug candidates will receive marketing approval.

We may seek breakthrough therapy designation for some of our current or future drug candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. The FDA has granted breakthrough therapy designation to avapritinib for the treatment of moderate to severe indolent SM. In addition, the FDA previously granted breakthrough designation to our drugs, AYVAKIT and GAVRETO, for the treatment of certain patients with GIST, advanced SM and RET-altered cancers, respectively.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug candidate may not result in a faster development process, review or approval compared to other drugs and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification.

We have in the past and may in the future seek approval of our product candidates, where applicable, under the FDA's accelerated approval pathway. This pathway may not lead to a faster development, regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of our product candidates, where applicable, under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM), that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of accelerated approval, the FDA likely would require that we perform adequate and well-controlled post-marketing clinical trials to confirm the product's clinical benefit. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

We may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

The FDA has granted orphan drug designation to avapritinib for the treatment of GIST and the treatment of mastocytosis, to pralsetinib for the treatment of RET-rearranged NSCLC, JAK1/2-positive NSCLC or TRKC-positive NSCLC and to fisogatinib for the treatment of HCC. In addition, the European Commission has granted medicinal product designation to avapritinib for the treatment of GIST and the treatment of mastocytosis. As part of our business strategy, we may seek orphan drug designation for some of our other drug candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the U.S. and the European Union (EU), may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers.

Similarly, in the EU, the European Commission grants orphan medicinal product designation after receiving the opinion of the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products on an orphan medicinal product designation application. Orphan medicinal product designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life threatening or chronically debilitating conditions affecting not more than five (5) in ten thousand (10,000) persons in the EU and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized for marketing in the EU (or, if such a method exists, the drug would be of significant benefit to those affected by the condition). In addition, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the EU would generate sufficient return to justify the necessary investment in developing the drug. In the EU, orphan medicinal product designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the U.S. and ten years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan medicinal product designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is

approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017 (FDARA). FDARA, among other things, codified the FDA's preexisting regulatory interpretation, to require that a drug Sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The law reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we intend to continue seek orphan drug designation for our drug candidates, we may never receive such designations. Even if we receive orphan drug designation for any of our drug candidates, there is no guarantee that we will enjoy the benefits of those designations.

The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

We may not be successful in our efforts to expand our pipeline of drug candidates.

A key element of our strategy is to use our novel target discovery engine to identify kinases that are drivers of diseases in genomically defined patient populations with high unmet medical need in order to build a pipeline of drug candidates. Although our research and development efforts to date have resulted in a pipeline of drug candidates, we may not be able to continue to identify novel kinase drivers and develop drug candidates. We may also pursue opportunities to acquire or in-license additional businesses, technologies or drugs, form strategic alliances or create joint ventures with third parties to complement or augment our existing business. For example, in February 2022 we entered into a collaboration with Proteovant to research and advance novel targeted protein degrader therapies leveraging Proteovant's artificial intelligence-enhanced targeted protein degradation platform and our small molecule precision medicine capabilities. However, we may not be able to identify any drug candidates for our pipeline through such acquisitions or in-licenses.

Even if we are successful in continuing to build and expand our pipeline, the potential drug candidates that we identify may not be suitable for clinical development. For example, they may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will be successful in clinical trials or receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize drug candidates, we will not be able to obtain drug revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited human capital and financial resources, we focus on research programs and drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our

spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

At any time and for any reason, we may determine that one or more of our discovery programs or preclinical or clinical drug candidates or programs does not have sufficient potential to warrant the allocation of resources toward such program or drug candidate. Accordingly, we may choose not to develop a potential drug candidate or elect to suspend, deprioritize or terminate one or more of our discovery programs or preclinical or clinical drug candidates or programs. If we suspend, deprioritize or terminate a program or drug candidate in which we have invested significant resources, we will have expended resources on a program that will not provide a full return on our investment and may have missed the opportunity to have allocated those resources to potentially more productive uses, including existing or future programs or drug candidates.

We intend to develop drug candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop, launch and commercialize BLU-945, BLU-701, BLU-222 and potentially other drug candidates in combination with one or more approved or unapproved therapies. Even if any drug candidate we develop were to receive marketing approval for use in combination with other approved therapies, the FDA, the EMA or other regulatory authorities could still revoke approval of the therapy used in combination with our drug candidate. If the therapies used in combination with our drug candidates are replaced as the standard of care for the indications we choose for any of our drug candidates, the FDA, EMA or regulatory authorities may require us to conduct additional clinical trials which may experience complications surrounding trial execution, such as complexities surrounding trial design, establishing trial protocols and interpretability of results, clinical site access and initiation, patient recruitment and enrollment, quality and supply of clinical doses, safety issues or a lack of clinically relevant activity. The uncertainty resulting for the use of our product candidates in combination with other approved or unapproved therapies may make it difficult to accurately predict side effects in the future clinical trials. The occurrence of any of these risks could result in our own drug candidates, if approved, being removed from the market if they are not also approved as monotherapies or being less successful commercially.

Further, we will not be able to market and sell any drug candidate we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our drug candidate. In addition, unapproved therapies face the same risks described with respect to our drug candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA, EMA or other regulatory authorities do not approve these other products or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the agents we choose to evaluate in combination with our drug candidates we may be unable to obtain approval of or market such combination therapy.

Risks Related to Government Legislations and Regulations

We are required to comply with comprehensive and ongoing regulatory requirements for any of our current or future approved drugs, including conducting confirmatory clinical trials for any drug that receives accelerated approval. In addition, our current or future approved drugs could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drugs.

We have in the past and may in the future seek approval of current or future product candidates, where applicable, under the FDA's accelerated approval pathway. Any current or future drug candidate for which we receive accelerated approval from the FDA, including GAVRETO, or similar conditional approval from the EMA, including AYVAKYT, or comparable regulatory authorities in other jurisdictions may be required to undergo one or more confirmatory clinical trials, as a condition of accelerated approval, be required to perform adequate and well-controlled post-marketing clinical trials to confirm the product's clinical benefit. These post-market confirmatory trials must be completed according to timelines agreed upon with the FDA. If such drug candidate fails to meet its safety and efficacy

endpoints in such confirmatory clinical trials, the regulatory authority may withdraw its approval. There is no assurance that any such drug candidate will successfully advance through its confirmatory clinical trial(s). Therefore, even if a drug candidate receives accelerated approval from the FDA or similar conditional approval from the EMA or comparable regulatory authorities, such approval may be withdrawn at a later date.

If the FDA or a comparable foreign regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practices (cGMPs) and Good Clinical Practices (GCPs) for any clinical trials that we conduct post approval. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the drug. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with our third party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, “dear doctor” letters or drug recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of marketing approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

The FDA’s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Regulatory agencies may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice (DOJ), closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers’ communications regarding off-label use, and if we, or any future collaborators, do not market any of our products for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing, government investigations, or litigation. Violation of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

Even if we are able to commercialize any of our approved drugs or drug candidates, if approved, such drug or drug candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the drug candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the drug candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval.

Our ability to commercialize any drugs and drug candidates successfully also will depend in part on the extent to which coverage and reimbursement for these drugs and drug candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize additional products will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of these or other products that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our products. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We cannot be sure that coverage will be available for any drug candidate that we commercialize and, if coverage is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval. Further, due to the ongoing COVID-19 pandemic, many individuals have lost or will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products. It is unclear what effect, if any, American Rescue Plan and other government efforts to expand coverage will have on the number of covered individuals. See section entitled “Business – Coverage and Reimbursement” included in our Annual Report on Form 10-K for the year ended December 31, 2021.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the U.S. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower-cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they

may be sold at lower prices than in the U.S. Private third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The United States has enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current drug candidates or any future drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. See section entitled “Business – Coverage and Reimbursement” included in our Annual Report on Form 10-K for the year ended December 31, 2021.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We may face competition in the U.S. for our development candidates and investigational medicines, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability. For example, on July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition which could adversely impact our business.

The Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act) was enacted in 2019 requiring sponsors of approved new drug applications and biologics license applications to provide sufficient quantities of product samples on commercially reasonable, market-based terms to entities developing generic drugs and biosimilar biological products. The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. If we are required to provide product samples or allocate additional resources to responding to such requests or any legal challenges under this law, our business could be adversely impacted.

Other legislative measures have also been enacted that may impose additional pricing and product development pressures on our business, and we expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our drugs and drug candidates, if approved, or additional pricing pressures.

We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our approved drugs and drug candidates.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Our arrangements with third-party payors and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including but not limited to, the federal healthcare Anti-Kickback Statute, the False Claims Act, the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Physician Payment Sunshine Act, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), the federal false statements statute, federal consumer protection and unfair competition laws and similar state and foreign laws and regulations that may regulate the business or financial arrangements and relationships through which we market, sell and distribute our drugs. The number and complexity of federal, state, and foreign laws continue to increase, and additional governmental resources are being used to enforce these laws and to prosecute companies and individuals who are believed to be violating them. See section entitled “Business – Other Healthcare Laws” included in our Annual Report on Form 10-K for the year ended December 31, 2021.

In the U.S., to help patients who have no or inadequate insurance access our drug, we have a patient assistance program that we administer in conjunction with our patient support program vendor. If we or our vendors are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses and reduce the availability of assistance to our patients.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize current or future drug candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our drug candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials, manufacturing, commercial sales, pricing and distribution of our drug candidates, and we cannot predict success in these jurisdictions. If we seek to develop our drug candidates or obtain approval of our drug candidates and ultimately commercialize our drug candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers’ ability to obtain reimbursement for our drug candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;

- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, including the European General Data Protection Regulation 2016/679, commonly referred to as GDPR;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our drug candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Governments outside the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly countries in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Risks Related to Our Financial Position and Need for Additional Capital

We are a precision therapy company with a limited operating history. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We are a precision therapy company with a limited operating history. To date, we have not yet demonstrated our ability to conduct large-scale sales and marketing activities necessary for successful commercialization. We currently have two approved precision therapies and are transitioning to a company capable of supporting commercial activities. We may not be successful in such a transition.

We commenced operations in April 2011 and we have focused substantially all of our efforts and financial resources to date on organizing and staffing our company, business planning, raising capital, establishing our intellectual property building our discovery platform, including our proprietary compound library and new target discovery engine, identifying kinase drug targets and potential drug candidates, conducting preclinical studies and clinical development for our drug candidates, commencing pre-commercial activities and the commercial launches for AYVAKIT/AYVAKYT and GAVRETO, and producing the active pharmaceutical ingredient (API), drug substance and drug product material for use in preclinical studies and clinical trials for our drug candidates and commercial sale of our approved drugs.

To date, we have financed our operations primarily through public offerings of our common stock, private placements of our convertible preferred and common stock, collaborations and a license agreement. Through March 31, 2022, we have received an aggregate of $3.0 billion from such transactions, including $1.9 billion in aggregate gross proceeds from the sale of common stock in our initial public offering, follow on public offerings, through our “at the market” stock offering program and the equity investment by Roche, $115.1 million in gross proceeds from the issuance of convertible preferred stock, $1.0 billion in upfront payments and milestone payments under our collaborations with Roche, CStone and Zai Lab our license agreement with Clementia and our former collaboration with Alexion. In addition, since January 2020, we also have generated revenue through sales of our drug products.

Since inception, we have incurred significant operating losses, with the exception of the year ended December 31, 2020. Our net loss was $106.0 million for the three months ended March 31, 2022. For the year ended December 31, 2021, our net loss was $644.1 million, which included $260.0 million of expenses related to the acquisition of Lengo, and our net income was $313.9 million for the year ended December 31, 2020 primarily due to the collaboration revenue recorded under our collaboration with Roche for pralsetinib. Our net loss was $347.7 million for the year ended December 31, 2019. As of March 31, 2022, we had an accumulated deficit of $1,381.4 million.

Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next few years. We anticipate that our expenses will continue to increase in connection with our ongoing activities. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ equity and working capital. We expect our research and development expenses to significantly increase in connection with continuing our existing clinical trials and beginning additional clinical trials. In addition, we will incur significant sales, marketing and outsourced manufacturing expenses in connection with the commercialization of any of our drugs or any drug candidates for which we may receive marketing approval. In addition, we have incurred and will continue to incur substantial costs associated with operating as a public company. Because of the numerous risks and uncertainties associated with developing pharmaceuticals, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate substantial revenue.

To date, we have not generated substantial revenue from drug sales. Our ability to generate substantial revenue depends on a number of factors, including, but not limited to, our ability to:

- initiate and successfully complete clinical trials that meet their clinical endpoints;

- initiate and successfully complete all safety studies required to obtain U.S. and foreign marketing approval for our drug candidates, including for avapritinib and pralsetinib for additional indications or in additional geographies;

- continue to maintain and expand commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;

- maintain and, if necessary, expand a sales, marketing and distribution infrastructure to commercialize AYVAKIT/AYVAKYT, GAVRETO and any current or future drug candidates for which we obtain marketing approval; and

- achieve market acceptance in the medical community and with third-party payors for AYVAKIT/AYVAKYT, GAVRETO and any current or future drug candidates for which we receive marketing approval.

We expect to incur significant sales and marketing costs as we commercialize AYVAKIT/AYVAKYT, jointly commercialize GAVRETO with Roche and commercialize any current or future drug candidates for which we receive marketing approval. Even if we initiate and successfully complete pivotal clinical trials of our drug candidates, and our drug candidates are approved for commercial sale, and despite expending these costs, our drug candidates may not be commercially successful. We may not achieve profitability soon after generating drug sales, if ever. If we are unable to generate substantial drug revenue, we will not become profitable and may be unable to continue operations without continued funding.

We may seek to raise additional funding from time to time. If we are unable to raise capital when needed, we may be forced to delay, reduce or eliminate some of our drug development programs or commercialization efforts.

The development and commercialization of pharmaceuticals is capital-intensive. We are currently advancing multiple drug candidates and development programs through clinical and preclinical development. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate or continue clinical trials of, and seek marketing approval for our drug candidates, including marketing approval for avapritinib for additional indications or in additional geographies and for pralsetinib. In addition, we expect to incur additional significant commercialization expenses for AYVAKIT/AYVAKYT, GAVRETO and other drug candidates, if approved, related to drug sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of potential collaborators or licensors. We may also need to raise additional funds if we choose to pursue additional indications or geographies for any of our approved drugs or drug candidates or otherwise expand more rapidly than we presently anticipate.

Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the success of our commercialization efforts and market acceptance for AYVAKIT/AYVAKYT, GAVRETO or any of our current or future drug candidates for which we receive marketing approval;

- the costs of maintaining, expanding or contracting for sales, marketing and distribution capabilities in connection with commercialization of AYVAKIT/AYVAKYT, GAVRETO and any of our current or future drug candidates for which we receive marketing approval;

- the costs of securing manufacturing, packaging and labeling arrangements for development activities and commercial production, including API, drug substance and drug product material for use in preclinical studies, clinical trials, our compassionate use program and for use as commercial supply, as applicable;

- the cost of purchasing quantities of agents for use in our clinical trials in connection with our efforts to develop our drugs and drug candidates, including for development as combination therapies;

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our approved drugs and drug candidates;
- the costs, timing and outcome of regulatory review of marketing applications for our drug candidates, including seeking marketing approval for avapritinib and pralsetinib for additional indications or in additional geographies;
- the success of our collaborations with Roche, CStone and Zai Lab and our license agreement with Clementia, as well as our ability to establish and maintain additional collaborations, partnerships or licenses on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under our existing collaboration or license agreements, or any collaboration, partnership or license agreements that we may enter into in the future;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, research and development, clinical or other costs under future collaboration agreements, if any;
- the extent to which we acquire or in-license other approved drugs, drug candidates or technologies and the terms of any such arrangements;
- the success of our current or future collaborations for the development and commercialization of companion diagnostic tests;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the costs of continuing to expand our operations.

Accordingly, we may seek additional funding in connection with our continuing operations or business objectives. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize any of our approved drugs or drug candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. We could also be required to seek funds through collaborations, partnerships, licensing arrangements or otherwise at an earlier stage than would be desirable and we may be required to relinquish rights to some of our technologies, drugs or drug candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis or on attractive terms, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any of our approved drugs or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

Until such time, if ever, as we can generate substantial drug revenues, we expect to finance our cash needs primarily through a combination of public and private equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds, other than our collaborations with Roche, CStone and Zai Lab and the license agreement with Clementia, which are limited in scope and duration and subject to the achievement of milestones or royalties on sales of licensed products, if any. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common stockholders. Debt financing, if available,

would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs, drugs or drug candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market drugs and drug candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to Our Dependence on Third Parties

We have entered into collaborations and licenses with our partners for the development and commercialization of several of our drugs and drug candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these drugs and drug candidates.

We have entered into collaborations and licenses with Roche, CStone, Zai Lab, Proteovant and Clementia, for the development and commercialization of several of our drugs and drug candidates, and may enter into additional collaborations and licenses with other third parties in the future. The success of these arrangements will depend heavily on the efforts and activities of our collaborators and licensing partners. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. In some situations, we may not be able to influence our collaboration partners' decisions regarding the development and collaboration of our partnered drugs and drug candidates, and as a result, our collaboration partners may not pursue or prioritize the development and commercialization of those partnered drugs and drug candidates in a manner that is in our best interest. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable drug candidate and, in some cases, termination of the collaboration arrangement or result in litigation or arbitration, which would be time-consuming and expensive. Licensors generally have sole discretion in determining the efforts and resources that they will apply to the licensed products.

Collaborations and licenses with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. For example, in the fourth quarter of 2017, Alexion terminated our collaboration related to fibrodysplasia ossificans progressiva for convenience following a strategic review by Alexion of its research and development portfolio. Any termination or expiration of our collaboration or license agreements with Roche, CStone, Zai Lab, Proteovant or Clementia, or of any future collaboration or license agreement, could adversely affect us financially or harm our business reputation.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, CROs, contract laboratories and other third parties to conduct or otherwise support clinical trials for our approved drugs and drug candidates. We rely heavily on these parties for execution of clinical trials for our drugs and drug candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs are required to comply with regulations, including GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and

trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our current or future clinical trials comply with GCPs. In addition, our clinical trials must be conducted with drug candidates produced under cGMPs regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design and sponsor the clinical trials for our approved drugs and drug candidates, CROs will conduct all of our clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct current or future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

Some of these factors may be beyond our control. For example, the performance of our CROs may also be delayed or disrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, availabilities of staff, exposure of CRO staff to COVID-19 or re-prioritization of CRO resources as a result of the pandemic. These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our approved drugs for additional indications and our drug candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our drug candidates, or our development program materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug for additional indications or our drug candidates. As a result, we believe that our financial results and the commercial prospects for our drugs or our drug candidates in the subject indication would be harmed, our costs could increase and our ability to generate substantial revenue could be delayed.

We contract with third parties for the manufacture of our approved drugs and drug candidates, including for preclinical, clinical and commercial supply. This reliance on third parties increases the risk that we will not have sufficient quantities of our approved drugs or drug candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, primarily on third parties for the manufacture of our drug

candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our current and future drugs. This reliance on third parties increases the risk that we will not have sufficient quantities of our drugs or drug candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our contract manufacturing organizations (CMOs) to manufacture our drugs and drug candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our CMOs for compliance with cGMPs in connection with the manufacture of our drugs and drug candidates. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drugs and drug candidates or is unable to conduct inspections necessary to approve these facilities due to delays or disruptions caused by the ongoing COVID-19 pandemic, or if the FDA or a comparable regulatory authority withdraws any such approval in the future, we may be delayed in obtaining approval of these facilities for the manufacture of our drugs and drug candidates or need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved, and could require comparability studies for the setup of manufacturing operations at alternative facilities. If any CMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply or commercial distribution could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, in the case of the CMOs that supply our product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or drugs, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our drugs and drug candidates.

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar

restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

We do not have long-term supply agreements with all of our CMOs, and may purchase our required drug supply, including the API, drug product and drug substance used in our drugs and drug candidates, on a purchase order basis with certain CMOs. In addition, we may be unable to establish or maintain any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish and maintain agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any of our drugs and drug candidates that we may develop may compete with other approved drugs and drug candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. In March 2020, the U.S. enacted the CARES Act in response to the U.S. COVID-19 pandemic. Throughout the ongoing COVID-19 pandemic, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances FDA's existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan in place that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for all of our bulk drug substances. If our current CMOs cannot perform as agreed, we may experience shortages that require reporting to the FDA or foreign regulatory authorities and may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our approved drugs and drug candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our drugs or drug candidates could result in significant delays or gaps in availability of such drugs or drug candidates and may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

The third parties upon whom we rely for the supply of the API, drug substance and drug product used in avapritinib and pralsetinib are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The API, drug substance and drug product used in our drug and drug candidates are supplied to us primarily from single-source suppliers. Our ability to successfully develop our drug candidates, supply our drug candidates for clinical trials and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API, drug substance and drug product for these drugs in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. Although we have entered into arrangements to establish redundant or second-source supply of some of the API, drug product or drug substance for avapritinib and pralsetinib, if any of our suppliers ceases its operations for any reason or is unable or unwilling to supply API, drug product or drug substance in sufficient quantities or on the timelines necessary to meet our needs, including as a result of the ongoing COVID-19 pandemic, it could significantly and adversely affect our business, the supply of our drug candidates or approved drugs and our financial condition.

For all of our drug candidates, we may from time to time explore opportunities to identify and qualify additional manufacturers to provide such API, drug substance and drug product prior to submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers. In addition, we currently have sufficient supply or plans for supply to meet our anticipated global commercial and clinical development needs for our approved drugs and clinical-stage drug candidates through 2022. However, the ongoing COVID-19 pandemic could adversely impact our suppliers and result in delays or disruptions in our current or future supply chain.

Establishing additional or replacement suppliers for the API, drug substance and drug product used in our drug candidates or approved drugs, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the API, drug substance and drug product used in our drug candidates and approved drugs, any interruption or delay in the supply of components or materials, or our inability to obtain such API, drug substance and drug product from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

Certain of our research and development, clinical trials and manufacturing and supply for certain raw materials used in our drugs and our drug candidates takes place in China through third-party CROs, collaborators or manufacturers. A significant disruption in the operation of those CROs, collaborators or manufacturers, could materially adversely affect our business, financial condition and results of operations.

We have relied on certain third parties located in China to manufacture and supply certain raw materials used in our drugs and our drug candidates, and we expect to continue to use such third party manufacturers for such purposes. In addition, certain of our drug candidates are being evaluated at clinical trial sites in China under our collaboration with CStone and through CROs located in China. A natural disaster, epidemic or pandemic disease outbreaks, including the ongoing COVID-19 pandemic, trade war, political unrest or other events in China could disrupt the business or operations of CROs, collaborators, manufacturers or other third parties with whom we conduct business now or in the future. Any disruption in China that significantly impacts such third parties, including services provided by CROs for our research and development programs, clinical trial operations conducted by CROs or our collaborators, or our manufacturers ability to produce raw materials in adequate quantities to meet our needs could impair our ability to operate our business on a day-to-day basis and impede, delay, limit or prevent the research, development or commercialization of our current and future approved drugs or drug candidates. In addition, for any activities conducted in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions in China, and we may be exposed to fluctuations in the value of the local currency in China for goods and services. Our costs for any of these services or activities could also increase as a result of future appreciation of the local currency in China or increased labor costs if the demand for skilled laborers increases in China and the availability of skilled labor declines in China.

Risks Related to Intellectual Property

If we are unable to adequately protect our proprietary technology or obtain and maintain patent protection for our technology and drugs or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the U.S. and other countries for our drugs and drug candidates and our core technologies, including our novel target discovery engine and our proprietary compound library and other know-how. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the U.S. and abroad related to our proprietary compounds, as well as the use of these compounds in the treatment of diseases, formulations, solid state forms, and manufacturing processes and other technologies, inventions and improvements that

are important to the development and implementation of our business. We also rely on copyright, trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

We own or license patents and patent applications that relate to our approved drugs AYVAKIT® (avapritinib) and GAVRETO® (pralsetinib) and our drug candidates fisogatinib, BLU-263, BLU-945, BLU-701, BLU-451 and BLU-222. We also own or license patents and patent applications relating to other compounds that are inhibitors of KIT and PDGFRA, FGFR4, RET, EGFR and CDK2, as well as methods of use, formulations, solid state forms, and manufacturing processes. The issued U.S. patent directed to AYVAKIT® composition of matter has a statutory expiration date in 2034, the issued U.S. patent directed to GAVRETO® composition of matter has a statutory expiration date in 2036.

As of April 15, 2022, the patent portfolio for our KIT and PDGFRA program, including AYVAKIT® and BLU-263 contains 12 issued U.S. patents, 19 issued foreign patents, including one European patent validated in 38 countries, five pending U.S. non-provisional patent applications, one pending U.S. provisional application, six pending PCT international patent applications and 50 pending foreign patent applications. The patents that have issued or will issue covering our KIT and PDGFRA program will have a statutory expiration date between 2034 and 2042. Patent term adjustments, patent term extensions, and supplementary protection certificates could result in later expiration dates.

As of April 15, 2022, the patent portfolio for our RET program, including GAVRETO® contains nine issued U.S. patents, four pending U.S. non-provisional patent applications, one U.S. provisional patent application, three pending PCT international applications, 55 pending foreign patent applications and 13 issued foreign patents. The patents that have issued or will issue covering our RET program will have a statutory expiration date between 2036 and 2042. Patent term adjustments, patent term extensions, and supplementary protection certificates could result in later expiration dates.

As of April 15, 2022, the patent portfolio for our FGFR4 program, including fisogatinib contains nine issued U.S. patents, two pending U.S. non-provisional patent applications, one pending PCT international application, 18 pending foreign patent applications and 31 issued foreign patents. The patents that have issued or will issue covering our FGFR4 program will have a statutory expiration date between 2033 and 2040. Patent term adjustments, patent term extensions, and supplementary protection certificates could result in later expiration dates.

As of April 15, 2022, the patent portfolio for our EGFR program, including BLU-945, BLU-701, and BLU-451 contains one issued U.S. patent, two pending U.S. non-provisional patent applications, 14 pending U.S. provisional applications, five pending PCT international patent applications and 23 pending foreign patent applications and two issued foreign patents, including one European patent validated in 6 countries directed to our EGFR program, including BLU-945, BLU-701, and BLU-451. The patents that have issued or will issue covering our EGFR program will have a statutory expiration date between 2034 and 2043. Patent term adjustments, patent term extensions, and supplementary protection certificates could result in later expiration dates.

As of April 15, 2022, the patent portfolio for our CDK2 program, including BLU-222 contains four pending U.S. provisional applications. The patents that will issue covering our CDK2 program will have a statutory expiration date of 2042. Patent term adjustments, patent term extensions, and supplementary protection certificates could result in later expiration dates.

The intellectual property portfolio directed to our platform includes patents and patent applications directed to novel gene fusions and the uses of these fusions for detecting and treating conditions implicated with these fusions. As of April 15, 2022, the patent portfolio directed to our platform contains nine issued U.S. patents, five pending U.S. non-provisional patent applications, three pending European Union patent applications and six issued European patents. Any U.S. or ex-U.S. patent issuing from the pending applications directed to this technology, if issued, will have statutory expiration dates ranging from 2034 to 2035.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation.

The degree of patent protection we require to successfully commercialize any of our approved drugs and drug candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us

to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our drugs and drug candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Furthermore, patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our drugs and drug candidates, including generic versions of such drugs or drug candidates.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same methods or formulations or the same subject matter, in either case, that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first-to-file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty. For example, we are aware of patents owned by third parties that have generic composition of matter, method of inhibition and method of treatment claims that may cover fisogatinib or generic method of treatment claims that may cover pralsetinib. If the claims of any of these third-party patents are asserted against us, we do not believe fisogatinib, pralsetinib or our proposed activities related to such compounds would be found to infringe any valid claim of these patents. While we may decide to initiate proceedings to challenge the validity of these patents in the future, we may be unsuccessful, and courts or patent offices in the U.S. and abroad could uphold the validity of any such patents. If we were to challenge the validity of any issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office (USPTO) have been significantly narrowed by the time they issue, if at all. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, there may be circumstances, when we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to maintain such competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our patents, which submissions may also be made prior to a patent's issuance, precluding the granting of any of our pending patent applications. We may become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights. Competitors may claim that they invented the inventions claimed in our issued patents or patent applications prior to us or may file patent applications before we do. Competitors may also claim that we are infringing on their patents and that we therefore cannot practice our technology as claimed under our patents, if issued. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees, consultants, advisors, and other third parties who have access to our proprietary know-how asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology, drugs and drug candidates. Such challenges may also result in our inability to manufacture or commercialize our drugs or drug candidates, if approved, without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drugs and drug candidates.

Even if they are unchallenged, our issued patents and our pending patents, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third party may develop a competitive drug that provides benefits similar to one or more of our drugs and drug candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our drugs and drug candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our drugs or drug candidates, if approved, could be negatively affected, which would harm our business.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our current and future drugs and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our drugs, drug candidates and technology, including interference proceedings before the USPTO. Our competitors or other third parties may assert infringement claims against us, alleging that our drugs are covered by their patents. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Many companies have filed, and continue to file, patent applications related to small molecule therapeutics. Some of these patent applications have already been allowed or issued, and others may issue in the future. For example, we are aware of patents owned by third parties that have generic composition of matter, method of inhibition and method of treatment claims that may cover fisogatinib or generic method of treatment claims that may cover pralsetinib. If the claims of any of these third-party patents are asserted against us, we do not believe fisogatinib, pralsetinib or our proposed activities related to such compounds would be found to infringe any valid claim of these patents. While we may decide to initiate proceedings to challenge the validity of these patents in the future, we may be unsuccessful, and courts or patent offices in the U.S. and abroad could uphold the validity of any such patents. If we were to challenge the validity of any issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims.

Since this area is competitive and of strong interest to pharmaceutical and biotechnology companies, there will likely be additional patent applications filed and additional patents granted in the future, as well as additional research and development programs expected in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our drugs and drug candidates. If a patent holder believes any of our approved drugs or drug

candidate infringes on its patent, the patent holder may sue us even if we have received patent protection for our drugs, drug candidates and technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our drug candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology, drugs or drug candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our current and future drugs or force us to cease some of our business operations, which could materially harm our business.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims. A court may disagree with our allegations, however, and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe their intellectual property or that a patent we have asserted against them is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid.

An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering any of our approved drugs or drug candidates, we would lose at least part, and perhaps all, of the patent protection covering such drug or drug candidate. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these outcomes would have a materially adverse effect on our business.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can

because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our drugs, drug candidates or procedures, we may not be able to stop a competitor from marketing drugs that are the same as or similar to our drugs or drug candidates, which would have a material adverse effect on our business.

We may not be able to effectively enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our drugs and drug candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, the patent laws of some foreign countries do not afford intellectual property protection to the same extent as the laws of the U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. Competitors may use our drugs, drug candidates and technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing drugs to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These drugs may compete with our drugs and drug candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in the major markets for our drugs and drug candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our drug candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Changes to the patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drugs and drug candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act (Leahy-Smith Act) signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the

validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first-to-file" system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to the protection afforded by patents, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. With respect to the building of our proprietary compound library, we consider trade secrets and know-how to be our primary intellectual property. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our consultants and employees. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors. Competitors could purchase our drugs and drug candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies, drugs, and drug candidates that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' drugs, our competitive position could be adversely affected, as could our business.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from

using technologies or features that are essential to our drugs or drug candidates if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our drugs and drug candidates, if approved. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drugs and drug candidates, if approved, which would have an adverse effect on our business, results of operations and financial condition.

Risks Related to Our Business, including Employee Matters, Managing Growth and Others

Our business, results of operations and future growth prospects could be materially and adversely affected by the ongoing COVID-19 pandemic.

Due to the continued evolution and uncertain global impacts of the ongoing COVID-19 pandemic and the identification of new variants of COVID-19, we cannot precisely determine or quantify the impact this pandemic will have on our business, operations and financial performance. The extent to which the ongoing COVID-19 pandemic may impact our business, results of operations and future growth prospects will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the duration, scope and severity of the pandemic, the duration and extent of travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat COVID-19.

For example, public health actions being undertaken globally in response to the ongoing COVID-19 pandemic, including quarantines, stay-at-home, executive and similar government orders and the prioritization of healthcare resources, could adversely impact our business, results of operations and future growth prospects. For ongoing and planned clinical trials, we anticipate and have experienced some temporary delays or disruptions due to the COVID-19 pandemic, including limited or reduced patient access to trial investigators, hospitals and trial sites, delayed initiation of new clinical trial sites and limited on-site personnel support at various trial sites, which could adversely impact our development plans, including the initiation of planned clinical trials, the rate of enrollment and our ability to conduct ongoing clinical trials. There may also be local orders affecting one or more trial sites, which may trigger mandated changes to our clinical trial protocols or temporary suspensions in the affected trial sites. In addition, quarantines, stay-at-home, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations have occurred and could continue to occur or be expanded in scope or duration, which could adversely impact:

- ongoing and planned clinical trials;
- our employees and business operations;
- personnel at our third-party suppliers and other vendors in the U.S. and other countries;
- the availability, cost or supply of materials, which may cause delays or disruptions to development plans for our drug candidates or clinical or commercial supply chains for our current or future approved drugs and drug candidates; and
- sales and marketing activities related to AYVAKIT/AYVAKYT, GAVRETO and any drug candidates for which we may receive marketing approval in the U.S. or other geographies in the future.

To the extent the ongoing COVID-19 pandemic adversely affects our business, results of operations and future growth prospects, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical, commercial, business development, financial and legal expertise of our executive officers, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of our executive officers may terminate their employment with us at any time. In addition, insurance coverage is increasingly expensive, including with respect to directors and officers liability insurance (D&O insurance). We may not be able to maintain D&O insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. An inability to secure and maintain D&O insurance may make it difficult for us to retain and attract talented and skilled directors and officers to serve our company, which could adversely affect our business. We do not maintain "key person" insurance for any of our executives or other employees.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to continue hiring qualified development personnel. Recruiting and retaining qualified scientific, clinical, regulatory, manufacturing and sales and marketing personnel is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing key employees and executive officers may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of April 15, 2022, we had 526 full-time and part-time employees, and we expect to continue to increase our number of employees and expand the scope of our operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Physical expansion of our operations in the future may lead to significant costs, including capital expenditures, and may divert financial resources from other projects, such as the development of our drug candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the ongoing COVID-19 pandemic has caused extreme volatility and disruptions in the capital and credit markets. In addition, geopolitical developments, such as the Russian invasion of Ukraine or

deterioration in the bilateral relationship between the U.S. and China could contribute to disruption, instability and volatility in the global markets, as well as an increased inflation, which in turn could adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions that may be initiated by nations including the U.S., the European Union or Russia (e.g., potential cyberattacks, disruption of energy flows) could adversely affect our business, our supply chain, CROs, CMOs, clinical trial sites, collaborative partners, or other third parties with which we conduct business. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our drug candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services.

Political development can also lead to uncertainty to regulations and rules that may materially affect our business. For example, as the UK regulatory system is now independent from the EU, Brexit could result in the UK significantly altering its regulations affecting the clearance or approval of our drug or drug candidates that are developed in the UK. Any new regulations could add time and expense to the conduct of our business, as well as the process by which our drug candidates receive regulatory approval in the UK, as compared to the European Union and elsewhere.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as clinical trial sites or the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business.

Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drugs' and drug candidates' development programs and have a material adverse effect on our reputation, business, financial condition or results of operations.

Our internal computer systems and those of our current or future third-party collaborators, service providers, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized groups and individuals with a wide range of motives and expertise. In addition to extracting sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The prevalent use of mobile devices also increases the risk of data security incidents. While we have not experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in a material disruption of our drugs' and drug candidates' development programs and significant reputational, financial, legal, regulatory, business or operational harm. For example, the loss of clinical trial data for our drugs or drug candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or drug candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our drug candidates could be delayed. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations to third parties, or any data security incidents or other security breaches that result in the unauthorized access, release or transfer of sensitive

information, including physician data, patient data, or any personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties asserting that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

Interruptions in the availability of server systems or communications with Internet or cloud-based services, or failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems, could harm our business.

We rely upon a variety of Internet service providers, third-party hosting facilities and cloud computing platform providers to support our business. Failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems could damage our reputation in the market, cause us to lose revenue or market share, increase our service costs, cause us to incur substantial costs, subject us to liability for damages and/or fines and divert our resources from other tasks, any one of which could materially adversely affect our business, financial condition, results of operations and prospects. Any damage to, or failure of, such systems, or communications to and between such systems, could result in interruptions in our operations. If our security measures or those of our third-party data center hosting facilities, cloud computing platform providers, or third-party service partners, are breached, and unauthorized access is obtained to our data or our information technology systems, we may incur significant legal and financial exposure and liabilities.

We do not have control over the operations of the facilities of our cloud service providers and our third party providers may be vulnerable to damage or interruption from natural disasters, cybersecurity attacks, terrorist attacks, power outages and similar events or acts of misconduct. In addition, any changes in our cloud service providers' service levels may adversely affect our ability to meet our requirements and operate our business.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.

Privacy and data security have become significant issues in the U.S., Europe and in many other jurisdictions where we conduct or may in the future conduct our operations. The regulatory framework for the collection, use, safeguarding, sharing and transfer of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. Notably, for example, on May 25, 2018, the European General Data Protection Regulation 2016/679, which is commonly referred to as GDPR, took effect. The GDPR applies to any company established in the EEA as well as any company outside the EEA that collects or otherwise processes personal data in connection with the offering goods or services to individuals in the EEA or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. The GDPR imposes additional obligations and risk upon our business and substantially increase the penalties to which we could be subject in the event of any non-compliance, including fines of up to €20 million or 4% of total worldwide annual turnover, whichever is higher. Further to the UK's exit from the European Union on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law (referred to as the 'UK GDPR'). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. In this document, "GDPR" refers to both the EU and the UK GDPR, unless specified otherwise. Given the breadth and depth of changes in data protection obligations, preparing for and complying with the GDPR requirements has required and will continue to require significant time, resources and a review of our technologies,

systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the EEA.

Further, European data protection laws also prohibit the transfer of personal data from the EEA and Switzerland to third countries that are not considered to provide adequate protections are provided for personal data, including the U.S. With regard to transfers of personal data from the EEA, transfers to third countries that have not been approved as "adequate" are prohibited unless an appropriate safeguard specified by the GDPR is implemented, such as the Standard Contractual Clauses (SCCs) approved by the European Commission or binding corporate rules, or a derogation applies. In 2020, the Court of Justice of the European Union (CJEU) deemed that transfers made pursuant to the EU SCCs and other alternative transfer mechanisms, including binding corporate rules, need to be analyzed on a case-by-case basis to ensure EU standards of data protection are met in the jurisdiction where the data importer is based, and there continue to be concerns about whether these transfer mechanisms will face additional challenges. European regulators have issued recent guidance following the CJEU case that imposes significant new diligence requirements on transferring data outside the European Union, including under an approved transfer mechanism. This guidance requires an "essential equivalency" assessment of the laws of the destination country transferred. If essentially equivalent protections are not available in the destination country, the exporting entity must then assess if supplemental measures can be put in place that, in combination with the chosen transfer mechanism, would address the deficiency in the laws and ensure that essentially equivalent protection can be given to the data.

On June 4, 2021, the European Commission issued new SCCs that account for the CJEU's decision and other developments, which need to be put in place for new contracts involving the transfer of personal data from the European Economic Area to a third country since September 27, 2021, and incorporated into existing contracts by December 27, 2022. The New SCCs do not apply to the UK, but the UK Information Commissioner's Office has published its own transfer mechanism, the International Data Transfer Agreement (UK IDTA), which entered into force on 21 March 2022, and enables data transfers originating from the UK. It requires a similar assessment of the data protection provided in the importer's country. The UK IDTA needs to be concluded in new contracts involving the transfer of personal data from the UK as of 22 September 2022. Organizations have until 21 March 2024 to update existing agreements. Complying with these obligations and applicable guidance regarding cross-border data transfers could be expensive and time consuming, and may require us to modify our data handling policies and procedures and may ultimately prevent or restrict us from transferring personal data outside the European Economic Area of the UK which could cause significant business disruption.

While we have taken steps to mitigate the impact on us with respect to transfers of data, such as implementing the SCCs in new contracts with our service providers, customers, subsidiaries, and are updating existing contracts with the new SCCs in anticipation of the December 2022 deadline, the validity of these transfer mechanisms remains uncertain. Complying with this guidance as it exists today and evolves will be expensive and time consuming and may ultimately prevent us from transferring personal data outside the European Union, which would cause significant business disruption for ourselves and our customers and potentially require the changes in the way our products are configured, hosted and supported.

In addition, we are subject to Swiss data protection laws, including the Federal Act on Data Protection (FADP). While the FADP provides broad protections to personal data, on September 25, 2020, the Swiss federal Parliament enacted a revised version of the FADP, which is anticipated to become effective in 2022 or the beginning of 2023. The new version of the FADP aligns Swiss data protection law with the GDPR.

Further, in addition to existing European data protection law, the European Union also is considering another draft data protection regulation. The proposed regulation, known as the Regulation on Privacy and Electronic Communications (ePrivacy Regulation), would replace the current ePrivacy Directive. The Draft Regulation is still the subject of negotiations between the Council of the European Union and the European Parliament. An update is expected in 2022. The aim is for the Draft Regulation to be in force some time in 2023. New rules related to the ePrivacy Regulation are likely to include enhanced consent requirements in order to use communications content and communications metadata, as well as obligations and restrictions on the processing of data from an end-user's terminal equipment, which may negatively impact our product offerings and our relationships with our customers.

Preparing for and complying with the evolving application of the GDPR, national laws in Switzerland and the UK, as well as ePrivacy Regulation (if and when it becomes effective) has required and will continue to require us to

incur substantial operational costs and may require us to change our business practices. Despite our efforts to bring practices into compliance with the GDPR, appliable national data protection laws and before the effective date of the ePrivacy Regulation, we may not be successful either due to internal or external factors such as resource allocation limitations. Non-compliance could result in proceedings, fines or penalties against us by governmental entities, customers, data subjects, consumer associations or others.

As another prominent example, we are also subject to data protection regulation in the UK. Following the UK's withdrawal from the EU on January 31, 2020 and the end of the transitional arrangements agreed between the UK and EU as of January 1, 2021, the GDPR has been incorporated into UK domestic law by virtue of section 3 of the European Union (Withdrawal) Act 2018 and amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (UK GDPR). United Kingdom-based organizations doing business in the European Union will need to continue to comply with the GDPR. Although the UK is regarded as a third country under the EU's GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The Information Commissioner's Office (ICO) has recently introduced new mechanisms for international transfers of personal data originating from the U.K. (an International Data Transfer Agreement, or IDTA, along with a separate addendum to the EU SCCs), which are in force as of March 21, 2022, to replace the old form EU SCCs for U.K. transfers. The new IDTA or the U.K. addendum must be used for any new contract entered into as of September 21, 2022 and implemented in existing contracts that incorporate the prior version of the SCCs by March 21, 2024. We will be required to implement these new safeguards when conducting restricted cross-border data transfers and doing so will require significant effort and cost. These and other future developments regarding the flow of data across borders could increase the cost and complexity of delivering our services in some markets and may lead to governmental enforcement actions, litigation, fines, and penalties or adverse publicity, which could adversely affect our business and financial position.

In addition to European data protection requirements, we are subject to the California Consumer Privacy Act (CCPA), which took effect on January 1, 2020 and imposes sweeping privacy and security obligations on many companies doing business in California and provides for substantial fines for non-compliance and, in some cases, a private right of action to consumers who are victims of data breaches involving their unredacted or unencrypted personal information. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. The CCPA became enforceable as of July 1, 2020, but there continues to be uncertainty about how the law will be interpreted and enforced.

Additionally, a new California ballot initiative, the California Privacy Rights Act (CPRA) was passed in November 2020. Effective starting on January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The effects of the CCPA and the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation.

Also, on March 2, 2021, Virginia enacted the Consumer Data Protection Act (CDPA). The CDPA will become effective January 1, 2023. The CDPA will regulate how businesses, which the CDPA refers to as "controllers", collect and share personal information. The law applies to companies that conduct business in Virginia or product products or services that are targeted to residents of Virginia and either: (1) annually control or process personal data of at least 100,000 Virginia residents; or (2) control or process the personal data of at least 25,000 Virginia residents and derive over 50% of gross revenue from the sale of personal data. While the CDPA incorporates many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of controllers. The new law will impact how controllers collect and process personal

sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. In addition, on July 8, 2021, Colorado's governor signed the Colorado Privacy Act (CPA) into law. The CPA is rather similar to the Virginia's CPDA but also contains additional requirements. The new measure applies to companies conducting business in Colorado or who produce or deliver commercial products or services intentionally targeted to its residents of the state and that either: (1) control or process the personal data of at least 100,000 Colorado residents during a calendar year; or (2) derive revenue or receive a discount on the price of goods or services from the sale of personal data and process or control the personal data of at least 25,000 Colorado residents.

Moreover, on March 24, 2022, Utah's governor signed the Utah Consumer Privacy Act (UCPA) into law. The UCPA will take effect on December 31, 2023. With the UCPA, which is largely based on Virginia's CDPA, Utah became the fourth state to enact a comprehensive privacy law but it is quite possible that other states will follow suit and bills have been proposed in many states. We expect anticipate that more states to may enact legislation similar to the CCPA and the other recent consumer privacy laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

The increasing number and complexity of regional, country and U.S. state data protection laws, and other changes in laws or regulations across the globe, especially those associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could lead to government enforcement actions and significant penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U.S. and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. In addition, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and

curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may acquire or in-license businesses, technologies or platforms, approved drugs, drug candidates or discovery-stage programs, or form strategic alliances, collaborations or partnerships, in the future, and we may not realize the benefits of such acquisitions, in-licenses, alliances, collaborations or partnerships.

We may acquire or in-license additional businesses, technologies or platforms, approved drugs, drug candidates or discovery-stage programs, or form strategic alliances, collaborations or partnerships that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs or drug candidates resulting from a strategic alliance, collaboration, partnership or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. In addition, we cannot assure you that, following any such transaction, we will achieve the expected synergies to justify the transaction.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. For tax years beginning after December 31, 2021, the Tax Cuts and Jobs Act of 2017 eliminates the once available option to deduct research and development expenditures currently and requires taxpayers to amortize them over five years. The U.S. Congress is considering legislation that would defer the amortization requirement to future periods; however, we have no assurance that the provision will be repealed or otherwise modified. If the requirement is not repealed or modified, it will have a material impact on the carryover of taxable losses used to offset future taxable income, and in turn, impacting our cash flows in future years.

Risks Related to Our Common Stock

The price of our common stock has been and may in the future be volatile and fluctuate substantially.

Our stock price has been and may in the future be subject to substantial volatility. For example, our stock traded within a range of a high price of $125.61 and a low price of $13.04 per share for the period beginning on April 30, 2015, our first day of trading on The Nasdaq Global Select Market, through February 15, 2022. As a result of this volatility, our stockholders could incur substantial losses.

The stock market in general has recently experienced relatively large price and volume fluctuations, particularly in response to the COVID-19 outbreak. In particular, the market prices of securities of Nasdaq listed and biopharmaceutical companies have experienced extreme fluctuations that often have been unrelated or disproportionate to the operating results of these companies. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could include a decline in the value of our common stock. In addition, the market price for our common stock may be influenced by many factors, including:

- the success of commercialization of our drugs and drug candidates, if approved;
- the success of competitive drugs or technologies;
- results of clinical trials of our drug candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;

- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our drug candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional drug candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- natural disasters, epidemic or pandemic disease outbreaks, including the COVID-19 pandemic, trade wars, political unrest or other similar events;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

Future sales or issuances of common stock or other equity related securities may also adversely affect the market price of our common stock. For example, In July 2020, we entered into a sales agreement with Cowen through which we may, from time to time, issue and sell shares of our common stock having an aggregate offering price of up to $250.0 million, subject to the terms and conditions of the sales agreement. In the year ended December 31, 2020, we issued and sold 1,784,926 shares of our common stock under the sales agreement at an average price of $112.05 per share for net and gross proceeds of $194.7 million and $200.0 million, respectively. We did not sell any shares of common stock under the sales agreement in the three months ended March 31, 2022. If we seek authorization to sell additional shares of common stock under the sales agreement, enter into new “at the market” stock offering programs, or conduct a public offering or private offering through other means, it could lead to additional dilution for our stockholders and may impact our stock price adversely.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

If equity research analysts publish negative evaluations of or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. If one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause our common stock price to decline.

Our executive officers, directors, principal stockholders and their affiliates maintain the ability to exercise significant influence over our company and all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially own shares of common stock representing a significant percentage of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of us.

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 attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Our bylaws contain exclusive forum provisions, which may limit a stockholder's ability to bring a claim in a judicial forum it finds favorable and may discourage lawsuits with respect to such claims.

Our amended and restated bylaws, as amended, or bylaws, provide that unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for state law claims for (1) any derivative action, (2) any claim of breach of fiduciary duty, (3) any claim against a current or former director, officer, employee or stockholder, and (4) any action against our company governed by the internal affairs doctrine, which we refer to collectively as the Delaware forum provision. The Delaware forum provision does not apply to any claims arising under the Securities Exchange Act of 1934 or the Securities Act of 1933, as amended, or the Securities Act. Our bylaws further provide that, unless we consent in writing to an alternative forum, the United States District Court for the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which we refer to as the federal forum provision. We have chosen the United States District Court for the District of Massachusetts as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Massachusetts. In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware forum provision and the federal forum provision.

The Delaware forum provision and the federal forum provision may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. In addition, these forum selection clauses in our bylaws may limit our stockholders'

ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The federal forum provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable or invalid. Alternatively, if the federal forum provision is found inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have an adverse effect on our business, financial condition or results of operations. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Future sales of our common stock, including by us or our directors and executive officers or shares issued upon the exercise of currently outstanding options, could cause our stock price to decline.

A substantial portion of our outstanding common stock can be traded without restriction at any time. In addition, a portion of our outstanding common stock is currently restricted as a result of federal securities laws, but can be sold at any time subject to applicable volume limitations. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, by us or others, could reduce the market price of our common stock or impair our ability to raise adequate capital through the sale of additional equity securities. In addition, we have a significant number of shares that are subject to outstanding options. The exercise of these options and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. We cannot predict the number, timing or size of future issuances or the effect, if any, that any future issuances may have on the market price for our common stock.

We have incurred and will continue to incur substantial costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred and expect to continue to incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission (SEC) and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and make some activities more time-consuming and costlier.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), we are required to furnish an annual report by our management on our internal control over financial reporting. To achieve compliance with Section 404 within the prescribed period, we have been and will continue to be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

Despite our efforts, there is a risk that in the future neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404 or that we will not be able to comply with the requirements of Section 404 in a timely manner. If this were to occur, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial

reporting, or financial results and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2021, we had federal net operating loss carryforwards of approximately $872.6 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us. In addition, pursuant to the TCJA (as amended by the CARES Act), we may not use net operating loss carry-forwards generated in taxable years beginning after December 31, 2017 to reduce our taxable income in any year beginning after December 31, 2020 by more than 80%, and we may not carry back any net operating losses to prior years. These rules apply regardless of the occurrence of an ownership change.

The Company recently completed an update to the prior Section 382 study dated February 25, 2021. Since the Section 382 owner shifts are tested on a cumulative basis, the current update incorporates the period from February 7, 2017, the day of the last identified ownership change, through December 31, 2021. The analysis concluded that it is more likely than not that an additional ownership change did not occur during the update analysis period. This is assuming that no further significant shifts in stock ownership have occurred by virtue of equity events that have not yet been reported in publicly available SEC filings.

As part of this update, the Company also analyzed the shifts in the stock ownership of Lengo Therapeutics, Inc. (Lengo), a company acquired on December 29, 2021, for purposes of determining (1) whether and when Lengo experienced an "ownership change," as defined in section 382(g)(1) of the Internal Revenue Code, during the period beginning March 6, 2019, the date of the first reported issuance of Lengo stock, and ending on the date of the Company's acquisition by Blueprint on December 29, 2021 (Owner Shift Analysis), and (2) the extent to which Lengo's net operating loss and tax credit carryforwards may be subject to limitation under sections 382 and 383 as a result of any such ownership changes (Limitation Analysis) (collectively, the Analysis). The analysis concluded that it is more likely than not that ownership changes occurred on (1) March 26, 2020 in connection with the issuance of Series A Preferred stock and (2) on December 29, 2021 in connection with Blueprint's acquisition of the Company.

Item 5. Other Information

On May 2, 2022, the Company delivered notice to Cowen and Company LLC ("Cowen") of its intent to terminate the previously existing Sales Agreement, dated July 30, 2020, by and between the Company and Cowen (the "Previous Sales Agreement"), pursuant to Section 11(c) of the Previous Sales Agreement. Cowen waived the 10 day advance notice requirement of Section 11(c), agreeing to terminate the Previous Sales Agreement effective as of May 2, 2022. The Previous Sales Agreement provided for the Company to offer and sell up to $250 million of shares of the Company's common stock from time to time in an at-the-market program through Cowen as the sales agent. For avoidance of doubt, the Sales Agreement dated as of February 17, 2022, by and between the Company and Cowen, is still in full force and effect.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1* †	Collaboration and License Agreement dated as of February 26, 2022 by and between Oncopia Therapeutics, Inc., d/b/a Proteovant Therapeutics, Inc. and the Registrant
10.2* †	Tenth Amendment to Collaboration and License Agreement, effective August 4, 2016, by and among F. Hoffmann-La Roche Ltd, Hoffmann-La Roche Inc. and the Registrant
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
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
101.INS	Inline XBRL Instance Document – the 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
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

* Filed herewith.

\# Indicates management contract or compensatory plan or arrangement.

† Certain portions of the exhibit have been omitted pursuant to Regulation S-K Item 601(b) because it is both (i) not material to investors and (ii) information that the Company treats as private or confidential.

\+ The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

BLUEPRINT MEDICINES CORPORATION

Date: May 3, 2022

By: /s/ Kathryn Haviland
Kathryn Haviland
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 3, 2022

By: /s/ Michael Landsittel
Michael Landsittel
Chief Financial Officer
(Principal Financial Officer)

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

EXECUTION VERSION

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (this "**Agreement**") is made and entered into as of February 26, 2022 (the "**Effective Date**") by and between **ONCOPIA THERAPEUTICS, INC.**, d/b/a **PROTEOVANT THERAPEUTICS, INC.**, a corporation organized under the laws of the State of Delaware, having its principal place of business at 151 W. 42nd St., 15th Floor, New York, New York 10036, USA ("**Proteovant**"), and **BLUEPRINT MEDICINES CORPORATION**, a corporation organized under the laws of the State of Delaware, located at 45 Sidney Street, Cambridge, MA 02139, USA ("**Blueprint**"). Proteovant and Blueprint are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, as a leading developer of targeted therapies for oncology and hematology, Blueprint owns or Controls certain Information and other Intellectual Property Rights related to the Research, Development and Commercialization of precision medicines, and possesses expertise that may contribute to the discovery and Development of protein degraders (as each term is defined below).

WHEREAS, Proteovant owns or Controls a suite of proprietary technologies that can be used to discover multiple types of protein degraders.

WHEREAS, Blueprint and Proteovant desire to collaborate in the performance of Target Programs for the purpose of discovery and Development of Collaboration Compounds suitable for Development for human therapeutic uses (as each term is defined below).

WHEREAS, Blueprint will have an exclusive option to obtain a worldwide, exclusive license to Develop and Commercialize Licensed Compounds and Licensed Products under such Target Programs, and Proteovant will have the right to opt into the global Development and U.S. Commercialization of certain of those Licensed Compounds and Licensed Products, all in accordance with the terms and conditions set forth in this Agreement (as each term is defined below).

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows.

1. DEFINITIONS

As used in this Agreement, the terms with initial letters capitalized, whether used in the singular or plural form, will have the meanings set forth in this Article 1 or, with respect to terms related to Proteovant's Opt-In Right, in **Schedule 1**.

1.1 "**AAA**" means the American Arbitration Association.

1.2 "**Accounting Standards**" means, with respect to either Party, generally accepted accounting principles as applicable in the U.S. or International Financial Reporting Standards of the International Accounting Standards Board, in each case, as generally and consistently applied throughout such Party's organization. Each Party will promptly notify the other Party in writing if such Party changes the Accounting Standards pursuant to which its records are maintained.

1.3 "**Acquired Party**" has the meaning set forth in Section 20.9(b)(iii).

1.4 "**Acquirer**" has the meaning set forth in Section 20.9(b)(iii).

1.5 "**Acquirer Technology**" has the meaning set forth in Section 20.9(b)(i).

1.6 "**Acquisition Transaction**" has the meaning set forth in Section 14.3.

1.7 "**Additional Collaboration Target**" has the meaning set forth in Section 2.5.

1.8 "**Additional Target Program**" has the meaning set forth in Section 2.5.

1.9 "**Additional Target Program Payment**" has the meaning set forth in Section 11.2.

1.10 "**Affiliate**" means, with respect to a particular Party, a Person that controls, is controlled by or is under common control with such Party, for so long as such control continues. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise. Notwithstanding anything in the foregoing, with respect to Proteovant, Affiliates of Proteovant do not include (a) [***] or its Affiliates, or (b) [***] or its Affiliates, in each case of (a) or (b), other than Proteovant or its subsidiaries (each an "**Excluded Affiliate**").

1.11 "**Agreement**" has the meaning set forth in the Preamble.

1.12 "**Alliance Manager**" has the meaning set forth in Section 9.11.

1.13 "**Antitrust Law**" means any federal, state or foreign law, regulation or decree, including the HSR Act, designed to prohibit, restrict or regulate actions for the purpose or effect of monopolization or restraint of trade.

1.14 "**Applicable Law**" means any applicable federal, state, local or foreign law, statute, ordinance, principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license or permit of any Governmental Authority.

1.15 "**Audited Party**" has the meaning set forth in Section 11.13.

1.16 "**Auditing Party**" has the meaning set forth in Section 11.13.

1.17 "**Available Target**" means a Target that, at the time the Parties seek to add such Target as a Replacement Collaboration Target or as an Additional Collaboration Target under this Agreement, as applicable: (a) is not a Target that is [***]; or (b) [***] under this Agreement for such Target.

1.18 "**Bankrupt Party**" has the meaning set forth in Section 20.3(a).

1.19 "**Blueprint**" has the meaning set forth in the Preamble.

1.20 "**Blueprint Claims**" has the meaning set forth in Section 18.1.

1.21 "**Blueprint Disclosure Date**" has the meaning set forth in Section 17.3.

1.22 "**Blueprint Indemnitees**" has the meaning set forth in Section 18.1.

1.23 "**Blueprint Know-How**" means all Information Controlled by Blueprint or, subject to Section 20.9(b), its Affiliate(s) as of the Effective Date or thereafter during the Term that is necessary or reasonably useful for the Research, Development, Manufacture, Medical Affairs, Commercialization or other Exploitation of Collaboration Compounds, Licensed Compounds and Licensed Products in the Field in the Territory.

1.24 "**Blueprint Patent Challenge**" has the meaning set forth in Section 16.6.

1.25 "**Blueprint Patents**" means all Patents that are Controlled by Blueprint or, subject to Section 20.9(b), its Affiliate(s) as of the Effective Date or thereafter during the Term that are necessary or reasonably useful for the [***].

1.26 "**Blueprint Target Binder Compound Know-How**" has the meaning set forth in Section 12.1(c)(ii).

1.27 "**Blueprint Target Binder Compound Patents**" has the meaning set forth in Section 12.1(c)(ii).

1.28 "**Blueprint Target Binder Compound Technology**" means the Blueprint Target Binder Compound Patents and the Blueprint Target Binder Compound Know-How.

1.29 "**Blueprint Target Binder Compounds**" means, for a given Target Program: (a) (i) any compounds [***] Controlled by Blueprint or its Affiliates and developed outside of this Agreement that are provided at Blueprint's sole discretion to Proteovant on a Target Program-by-

Target Program basis for use under a Research Plan, which compounds will be listed on **Schedule 1.29**; and (ii) the derivatives of any compounds described in clause (i) developed by or on behalf of either Party or jointly by the Parties under this Agreement, and in each case of (i) and (ii) [***]; [***]. Additional Blueprint Target Binder Compounds may be added in writing to **Schedule 1.29** by Blueprint in its sole discretion, including for use under a Research Plan for a Replacement Target Program or Additional Target Program.

1.30 "**Blueprint Technology**" means, collectively, the Blueprint Patents, Blueprint Know-How, Blueprint Target Binder Compound Patents and Blueprint Target Binder Compound Know-How.

1.31 "**Blueprint's Knowledge**" means with respect to Blueprint, [***].

1.32 "**Business Day**" means a day that is not a Saturday, Sunday or a day on which banking institutions in Boston, Massachusetts or New York, New York are required by Applicable Law to remain closed.

1.33 "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.34 "**Calendar Year**" means the one (1) year period beginning on January 1 and ending on December 31, except for the first year which will begin on the Effective Date and end on December 31.

1.35 "**CDx**" means a Third Party companion diagnostic for use with an Opt-In Product.

1.36 "**Change of Control**" means, with respect to a Party that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing at least fifty percent (50%) of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated which would result in shareholders or equity holders of such Party immediately prior to such transaction, owning at least fifty percent (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, through one or more related transactions. Notwithstanding the foregoing, a Change of Control will exclude a bona fide equity financing primarily for capital raising purposes and/or an IPO.

1.37 "**Claim**" has the meaning set forth in Section 18.3.

1.38 "**Clinical Trial**" means any human clinical trial of a Licensed Compound or Licensed Product.

1.39 "**CMC**" means chemistry, manufacturing and controls with respect to Collaboration Compounds, Licensed Compounds and Licensed Products, including the chemistry,

manufacturing and controls section of Regulatory Materials for Licensed Products and all data contained or referenced therein.

1.40 "**Co-Commercialization**" or "**Co-Commercialize**" or "**Co-Commercializing**" means, with respect to [***].

1.41 "**Co-Commercialization Agreement**" has the meaning set forth in Section 7.4(a).

1.42 "**Co-Development**" or "**Co-Develop**" or "**Co-Developing**" means, with respect to Proteovant, the Development activities assigned to Proteovant in the Opt-In Global Development Plan.

1.43 "**Collaboration**" has the meaning set forth in Section 9.1.

1.44 "**Collaboration Compound**" means with respect to a Target Program and applicable Research Plan: [***].

1.45 "**Collaboration Know-How**" means the Sole Know-How and the Joint Know-How.

1.46 "**Collaboration Patents**" means the Sole Patents and the Joint Patents.

1.47 "**Collaboration Target**" means, with respect to the Initial Target Programs, the Targets identified for such Target Programs on **Schedule 1.47**, each Additional Collaboration Target mutually agreed to by the Parties in accordance with Section 2.5 and each Replacement Collaboration Target mutually agreed to by the Parties in accordance with Section 2.4.

1.48 "**Collaboration Technology**" means the Collaboration Know-How and the Collaboration Patents.

1.49 "**Combination Product**" means a product that includes at least one additional active ingredient (each an "**Other Component**") (whether co-formulated or co-packaged) that is not a Collaboration Compound. [***]

1.50 "**Commercial Arbitration Rules**" has the meaning set forth in Section 19.3(b).

1.51 "**Commercialize**" or "**Commercialization**" or "**Commercializing**" means the marketing, promotion, detailing, sale and booking of sales or distribution of a Licensed Product in the Territory, including (a) market research matters including revenue forecasting, market landscape/situational analyses, competitive intelligence, material testing, dashboard reporting, health economics/value proposition, branding and communications plans, and pricing strategy, (b) field force matters, including field force training, field operations, performance metrics/reporting, field force sizing and alignment, key customer development, and professional education (to the extent not performed by field representatives), including launch meetings, (c) Health Services Matters, (d) peer-to-peer activities (such as 'lunch and learns'), and (e) market access and patient support services.

1.52 "**Commercially Reasonable Efforts**" means, with respect to the performance of an obligation under this Agreement, such level of efforts that are consistent with the efforts and resources [***].

1.53 "**Committee**" has the meaning set forth in Section 9.7.

1.54 "**Competing Product**" means, with respect to a Collaboration Target, [***].

1.55 "**Competitive Infringement**" has the meaning set forth in Section 12.8(a).

1.56 "**Confidential Information**" means, with respect to a Party, and subject to Section 15.1, all non-public Information of such Party that is disclosed to the other Party under this Agreement or the Prior CDA or generated under or in connection with the Research Plan, whether disclosed in oral, written, graphic, or electronic form; provided, that, notwithstanding the foregoing, (a) the existence and terms of this Agreement will be deemed to be the Confidential Information of both Parties and both Parties will be deemed to be the Receiving Party with respect thereto, (b) subject to Section 1.56(c), Joint Know-How and Joint Patents will be deemed to be the Confidential Information of both Parties, and both Parties will be deemed to be the Disclosing Party with respect thereto, and [***].

1.57 "**Control**" or "**Controlled**" means, with respect to any Material, Information, Patent or other Intellectual Property Right, that a Party or its Affiliate (a) owns such Material, Information, Patent or other Intellectual Property Right, or (b) has a license or right to use to such Material, Information, Patent or other Intellectual Property Right, in each case (a) or (b) with the ability to grant to the other Party access, a right to use, or a license, or a sublicense (as applicable) to such Material, Information, Patent or other Intellectual Property Right on the terms and conditions set forth herein, without violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use or (sub)license. Notwithstanding the foregoing, with respect to Acquirer Technology, the definition of "**Control**" is subject to the terms and conditions set forth in Section 20.9(b).

1.58 "**Cover**", "**Covered**" or "**Covering**" means, with respect to a Collaboration Compound, Licensed Compound or Licensed Product and a Patent, that, in absence of a (sub)license under, or ownership of, such Patent, the making, using, offering for sale, selling or importing of such Collaboration Compound, Licensed Compound or Licensed Product would infringe such Patent as issued or, with respect to a pending claim included in such Patent, as if such pending claim were to issue without modification.

1.59 "**Cure Period**" has the meaning set forth in Section 16.3(a).

1.60 [***].

1.61 [***].

1.62 "**Detail**" means, with respect to an Opt-In Target Program in the Opt-In Territory, a person-to-person (including, for clarity, e-details) contact between a sales representative and a physician or other medical professional licensed to prescribe drugs, during which a primary

position detail (as defined in the applicable Opt-In Commercialization Plan) or a secondary position detail (as defined in the applicable Opt-In Commercialization Plan) is made to such prescriber, in each case as measured by each Party's internal recording of such activity in accordance with the applicable Opt-In Commercialization Plan; provided that such meeting is consistent with and in accordance with the requirements of Applicable Law and this Agreement. When used as a verb, "**Detail**" means to engage in a Detail.

1.63 "**Develop**" or "**Developing**" or "**Development**" means, with respect to a Collaboration Compound and the corresponding Licensed Compound and Licensed Product(s), all activities after such Collaboration Compound achieves Development Candidate status as set forth in the applicable Research Plan, that relate to obtaining, maintaining or expanding Regulatory Approval of such Collaboration Compound and the corresponding Licensed Compound and Licensed Product(s), and developing the processes for the Manufacture of clinical and commercial quantities of such Collaboration Compound and the corresponding Licensed Compound and Licensed Product(s), and any Manufacturing in support thereof, including non-clinical and clinical Manufacturing. This includes: [***].

1.64 "**Development Candidate**" means each Collaboration Compound that the JRC [***].

1.65 [***].

1.66 [***].

1.67 [***].

1.68 [***].

1.69 "**Disclosing Party**" has the meaning set forth in Section 15.1, subject to the proviso in the definition of Confidential Information.

1.70 "**Discontinued Collaboration Target**" has the meaning set forth in Section 2.4.

1.71 "**Discontinued Target Program**" has the meaning set forth in Section 2.4.

1.72 "**Discussion Period**" has the meaning set forth in Section 10.3.

1.73 "**Dispute**" has the meaning set forth in Section 19.1.

1.74 "**Distracting Product**" has the meaning set forth in Section 14.3.

1.75 "**DOJ**" means the U.S. Department of Justice, and any successor agency thereto.

1.76 "**Dollar**" or "**$**" means the lawful currency of the U.S.

1.77 "**Effective Date**" means the date specified in the Preamble.

1.78 "**Eligible Opt-In Program**" has the meaning set forth in Section 4.1.

1.79 "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.80 "**EU**" or "**European Union**" means the European Union, as its membership may be constituted from time to time, and any successor thereto, and which, as of the Effective Date, consists of Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden and that certain portion of Cyprus included in such organization.

1.81 [***].

1.82 "**Executive Officer**" means, [***].

1.83 "**Existing Blueprint Patents**" has the meaning set forth in Section 17.3(a).

1.84 "**Existing Proteovant Patents**" has the meaning set forth in Section 17.2(a).

1.85 "**Expedited Arbitration**" has the meaning set forth in Section 19.4.

1.86 "**Expert**" means a mutually acceptable, disinterested, conflict-of-interest-free individual not affiliated with either Party or its Affiliates, or with respect to Proteovant, its Excluded Affiliates, who, with respect to a dispute concerning a financial, commercial, scientific or regulatory matter possesses appropriate expertise to resolve such dispute. The Expert (or any of the Expert's current or former employers) (a) will not be or have been at any time an Affiliate of either Party [***], employee, consultant (during the previous [***] years), officer or director of either Party or any of its Affiliates, or with respect to Proteovant, its Excluded Affiliates, or (b) will not own equity or debt in either Party or any of its Affiliates, [***] (other than equity or debt owned through a broad based mutual fund or exchange trade fund).

1.87 "**Exploit**" or "**Exploitation**" means, with respect to a Collaboration Compound and the corresponding Licensed Compound and Licensed Product(s), to make, have made, import, use, sell or offer for sale, including to Research, Develop, Commercialize, register, modify, enhance, improve, Manufacture, hold or keep (whether for disposal or otherwise), formulate, optimize, have used, export, transport, distribute, promote, market or have sold or otherwise dispose of such Collaboration Compound and the corresponding Licensed Compound and Licensed Product(s).

1.88 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.89 "**FD&C Act**" or "**Act**" means the United States Federal Food, Drug, and Cosmetic Act, as amended.

1.90 "**Field**" means the prevention, treatment, and diagnosis of any indications in humans.

1.91 "**First Commercial Sale**" means, with respect to a Licensed Product and a country, the first sale to a Third Party that is not a Related Party of such Licensed Product, as applicable, in

such country after Regulatory Approval of such Licensed Product has been obtained in such country. First Commercial Sale excludes [***].

1.92 "**force majeure**" has the meaning set forth in Section 20.4.

1.93 "**FTC**" means the U.S. Federal Trade Commission, and any successor agency thereto.

1.94 "**Future In-Licensed IP**" has the meaning set forth in Section 11.6(e).

1.95 "**[***]**" has the meaning set forth in [***].

1.96 "**[***]**" means, with respect to a Licensed Product in a country, [***] that (a) is [***] of such Licensed Product, including [***] or (b) is [***] for such Licensed Product [***].

1.97 "**Global Development Plan**" means the written Development plan intended to support Development and Regulatory Approval of Licensed Products in the Field in the Territory, as may be updated and amended periodically in accordance with Section 6.2(a).

1.98 "**GLP**" means applicable good laboratory practices as in effect in a relevant regulatory jurisdiction, including as required by the FDA under 21 C.F.R. Part 58 and all applicable FDA rules, regulations, orders, and guidances, and the requirements with respect to good laboratory practices prescribed by the European Community, the OECD (Organization for Economic Cooperation and Development Council), or as otherwise required by Applicable Law.

1.99 "**Governmental Authority**" means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court, tribunal or other entity).

1.100 "**Health Services Matters**" means (a) with respect to the Opt-In Territory, all services relating to payer and GPO engagement/contracting, reimbursement and other patient support services, government pricing, price reporting and related contracting in the Shared Territory, and (b) with respect to the Territory, other than the Opt-In Territory, all of the foregoing and health authority pricing and reimbursement negotiations and contracting.

1.101 "**HSR Act**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

1.102 "**IND**" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to the applicable Regulatory Authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction, or (c) any supplement or amendment to the foregoing.

1.103 "**Indemnified Party**" has the meaning set forth in Section 18.3.

1.104 "**Indemnifying Party**" has the meaning set forth in Section 18.3.

1.105 "**Indication**" means [***].

1.106 "**Information**" means any data, results, and information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, technical information, business information, unpublished patent applications, practices, models, techniques, methods, processes, inventions, discoveries, procedures, protocols, developments, specifications, formulations, formulae, software, source code, object code, algorithms, marketing reports, expertise, stability, technology, test data (including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data), manufacturing (including CMC) data, analytical and quality control data, studies and procedures.

1.107 "**Information Request**" has the meaning set forth in Section 2.3(e).

1.108 "**Initial Synthesis**" means, with respect to a Target Program, the preparation of a Collaboration Compound in sufficient quantities to perform Proteovant's activities under the applicable Research Plan.

1.109 "**Initial Target Programs**" has the meaning set forth in Section 2.1(a).

1.110 "**Initiation**" of a Clinical Trial will mean the [***] in the relevant Clinical Trial of a Licensed Compound or Licensed Product, as applicable, in accordance with the applicable protocol and Applicable Law.

1.111 "**Insolvency Event**" has the meaning set forth in Section 16.4.

1.112 "**Intellectual Property Rights**" (whether capitalized or not) means any and all intellectual property rights and industrial design rights, whether protected, created or arising under the laws of the U.S. or any foreign jurisdiction, including the following: (a) Patents; (b) copyrights, mask work rights, database rights and design rights, whether or not registered, published or unpublished, and registrations and applications for registration thereof, and all rights therein whether provided by international treaties or conventions or otherwise; (c) trade secret rights; (d) moral rights; (e) trademarks, service marks, trade names, service names, corporate names, trade dress, logos, and other identifiers of source, including all goodwill associated therewith and all common law rights, registrations and applications for registration thereof, and all rights therein provided by international treaties or conventions, and all reissues, extensions and renewals of any of the foregoing, and all intellectual property rights arising from or in respect of domain names, domain name registrations and reservations; and (f) other applications and registrations related to any of the rights set forth in the foregoing clauses (a) – (e) above which subsist now or will subsist in the future together with all rights of action, powers and benefits arising from ownership of any such rights.

1.113 "**IP Assignment Date**" has the meaning set forth in Section 12.1(c)(i).

1.114 "**IPO**" means the first underwritten public offering of equity securities of a Party (or any successor thereto formed for the purpose of pursuing an initial public offering) pursuant to an effective registration statement filed with the United States Securities and Exchange Commission (or any successor form) including a transaction with a special purpose acquisition company, plan of arrangement, amalgamation, direct listing, reverse take-over or other business

combination pursuant to which the securities of such Party, or any resulting issuer or parent entity thereof, are listed on a stock exchange; provided, that an IPO will not include any registration of the issuance of securities to existing securityholders or employees of a Party on Form S-4 or Form S-8 (or any successor forms).

1.115 "**Joint Commercialization Committee**" or "**JCC**" has the meaning set forth in Section 9.6(a).

1.116 "**Joint Confidential Information**" has the meaning set forth in Section 1.56.

1.117 "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 9.5(a).

1.118 "**Joint Know-How**" has the meaning set forth in Section 12.1(a).

1.119 "**Joint Patent**" has the meaning set forth in Section 12.1(a).

1.120 "**Joint Project Team**" or "**JPT**" has the meaning set forth in Section 9.3(a).

1.121 "**Joint Research Committee**" or "**JRC**" has the meaning set forth in Section 9.2(a).

1.122 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 9.4(a).

1.123 "**JPT Chairperson**" has the meaning set forth in Section 9.3(b).

1.124 "**JRC Chairperson**" has the meaning set forth in Section 9.2(b).

1.125 [***].

1.126 [***].

1.127 [***].

1.128 [***].

1.129 [***].

1.130 "**License Agreement**" means each agreement under which Blueprint grants a sublicense pursuant to Section 10.5 under the licenses set forth in Section 10.1.

1.131 "**Licensed Compound**" has the meaning set forth in Section 3.3(a).

1.132 "**Licensed Compound Information**" has the meaning set forth in Section 1.56.

1.133 "**Licensed Product**" means any product in any form or formulation containing a Licensed Compound, whether alone or as a Combination Product, in any dosage form, or formulation or method of delivery.

1.134 "**Licensed Target Program**" has the meaning set forth in Section 3.3(a).

1.135 "**Lien**" means any lien, pledge, encumbrance, mortgage, security interest, purchase option, call or similar right, conditional and installment sale agreements, charges or claims of any kind (excluding any license or other rights granted to Third Parties under any of the Proteovant Technology or, with respect to a Scheduled Blueprint Contributed Compound, the applicable Blueprint Target Binder Compound Technology, that do not conflict with or otherwise limit the rights granted to Blueprint or Proteovant, as applicable, under this Agreement).

1.136 [***] has the meaning set forth in [***].

1.137 "**MAA**" or "**Marketing Authorization Application**" means an NDA in the United States or an analogous application for a Licensed Product in another relevant jurisdiction in the Territory.

1.138 "**Major European Market**" means any of the following countries: [***].

1.139 "**Manufacture**" or "**Manufacturing**" means all activities related to the manufacturing of a drug product or any component or ingredient thereof (*e.g.*, any drug substance or intermediate thereof), including test method development and stability testing, formulation, process development, process qualification and validation, manufacturing scale-up whether before or after Regulatory Approval, manufacturing in bulk or finished form for Development or Commercialization (as applicable), filling and finishing, packaging, labeling, shipping and holding, in-process and finished product testing, release of a product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of a product, and submission to and correspondence with Regulatory Authorities related to any of the foregoing.

1.140 "**Materials**" means all biological materials, chemical compounds and other materials (a) arising out of a Party's activities under this Agreement and provided by such Party to the other Party for use by the other Party or (b) otherwise provided by a Party for use by the other Party, in each case, to conduct activities pursuant to this Agreement, including [***].

1.141 "**Merger Control Authority**" means all relevant Governmental Authorities under applicable Antitrust Laws, including the FTC and DOJ.

1.142 "**Metabolites**" means any intermediate products, catalytic products, end products, by-products, or any products created by metabolic breakdown by a bodily system.

1.143 "**NDA**" or "**New Drug Application**" has the meaning set forth as described in the FD&C Act and 21 C.F.R. Part 314.

1.144 "**Net Sales**" means, with respect to Licensed Products (including, for clarity, Opt-In Products) in the Territory, [***].

1.145 "**Nonclinical Studies**" means all non-human studies, including preclinical studies and toxicology studies, of Collaboration Compounds, Licensed Compounds and Licensed Products.

1.146 [***].

1.147 "**Non-Exclusively Licensed Schedule**" has the meaning set forth in Section 10.3.

1.148 "**Opening Brief**" has the meaning set forth in Section 19.4(b).

1.149 "**Opt-In Commercialization Plan**" has the meaning set forth in Section 7.3(a)(i).

1.150 "**Opt-In Compounds**" has the meaning set forth in Section 4.2.

1.151 "**Opt-In Exercise Date**" means the date on which the Opt-In Exercise Notice is delivered to Blueprint.

1.152 "**Opt-In Exercise Notice**" has the meaning set forth in Section 4.2.

1.153 "**Opt-In Exercise Period**" has the meaning set forth in Section 4.2.

1.154 "**Opt-In Global Development Budget**" has the meaning set forth in Section 6.3(a)(ii).

1.155 "**Opt-In Global Development Plan**" has the meaning set forth in Section 6.3(a)(i).

1.156 "**Opt-In Products**" has the meaning set forth in Section 4.2.

1.157 "**Opt-In Right**" has the meaning set forth in Section 4.1.

1.158 "**Opt-In Target Program**" has the meaning set forth in Section 4.2.

1.159 [***].

1.160 "**Opt-In Territory**" means the U.S.

1.161 "**Option**" has the meaning set forth in Section 3.1.

1.162 "**Option Exercise Date**" means [***].

1.163 "**Option Exercise Notice**" means the written notice Blueprint delivers to Proteovant to exercise an Option with respect to a Target Program.

1.164 "**Option Exercise Period**" has the meaning set forth in Section 3.2.

1.165 "**Other Component**" has the meaning set forth in Section 1.49.

1.166 "**Out-of-Pocket Costs**" means [***].

1.167 "**Parties**" and "**Party**" have the meaning set forth in the Preamble.

1.168 "**Patent**" means (a) all patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or

provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, patent cooperation treaty (PCT) applications, substitutions, reissues, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications in (a) and (b), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including adjustments, revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications in (a), (b) and (c), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patents of addition to any of such foregoing patent applications and patents, (a) through (e) above, anywhere in the world.

1.169 "**Patent Challenge**" has the meaning set forth in Section 12.10(a).

1.170 "**Patent Contact**" has the meaning set forth in Section 12.11.

1.171 "**Patent Prosecution Costs**" means the direct Out-of-Pocket Costs (including the reasonable fees and expenses incurred to outside counsel and other Third Parties, including fees incurred to Governmental Authorities) recorded as an expense by a Party or any of its Affiliates (in accordance with the Accounting Standards and its customary accounting practices) after the Effective Date and during the Term and pursuant to this Agreement, in connection with the preparation, filing, prosecution, maintenance and extension of Patents, including costs of the defense of any interference, appeal, opposition, reissue proceedings, reexamination, revocation, petitions or other post-grant or administrative proceedings with respect to Patents and filing and registration fees.

1.172 "**Performing Persons**" has the meaning set forth in Section 15.8(a).

1.173 "**Person**" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture company, Governmental Authority, association or other entity.

1.174 "**Phase 1 Clinical Trial**" means a Clinical Trial of a Licensed Compound or Licensed Product, the principal purpose of which is to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of such Licensed Compound or Licensed Product, which is prospectively designed to generate sufficient data (if successful) to commence a Phase 2 Clinical Trial (or later Clinical Trial) of such Licensed Compound or Licensed Product, as described in 21 C.F.R. 312.21(a), as amended from time to time, or a similar Clinical Trial described by the relevant Regulatory Authority or Applicable Law in a country other than the U.S.

1.175 "**Phase 2 Clinical Trial**" means a controlled Clinical Trial of a Licensed Compound or Licensed Product, the principal purpose of which is to evaluate the effectiveness of such Licensed Compound or Licensed Product for a particular Indication or Indications in patients with the relevant disease or condition under study and to determine the common short-term side effects and risks associated with such Licensed Compound or Licensed Product, as described in 21 C.F.R. § 312.21(b), as amended from time to time, or a similar Clinical Trial described by the relevant Regulatory Authority or Applicable Law in a country other than the U.S.

1.176 "**Phase 3 Clinical Trial**" means a Clinical Trial of a Licensed Compound or Licensed Product for a particular Indication or Indications in patients with the relevant disease or condition and that incorporates accepted endpoints to evaluate efficacy and safety of such Licensed Compound or Licensed Product with the aim to generate data and results that can provide an adequate basis for physician labeling and that can be submitted to seek Regulatory Approval as described in 21 C.F.R. 312.21(c), or a comparable Clinical Trial described by the relevant Regulatory Authority or Applicable Law in a country other than the U.S.

1.177 "**Post-Option Publication**" has the meaning set forth in Section 15.4(a).

1.178 "**Prior CDA**" means that certain Nondisclosure Agreement entered into by Blueprint and Proteovant effective as of [***].

1.179 "**Product Marks**" has the meaning set forth in Section 13.1.

1.180 "**Product Patent**" has the meaning set forth in Section 12.1(c)(i).

1.181 "**Product Specific Infringement Action**" has the meaning set forth in Section 12.8(b).

1.182 "**Progress Update**" has the meaning set forth in Section 14.1(b).

1.183 [***].

1.184 [***].

1.185 [***].

1.186 "**Prosecute**" or "**Prosecution**" has the meaning set forth in Section 12.2(a)(i).

1.187 "**Proteovant**" has the meaning set forth in the Preamble.

1.188 "**Proteovant Claims**" has the meaning set forth in Section 18.2.

1.189 "**Proteovant Disclosure Date**" has the meaning set forth in Section 17.2.

1.190 "**Proteovant Indemnitees**" has the meaning set forth in Section 18.2.

1.191 [***].

1.192 [***].

1.193 [***].

1.194 [***].

1.195 [***].

1.196 "**Proteovant Patents**" means all Patents that are Controlled by Proteovant or, subject to Section 20.9(b), its Affiliate(s) as of the Effective Date or thereafter during the Term that are [***]; provided that Proteovant Patents will not include Proteovant [***] Patents or [***] Patents.

1.197 "**Proteovant Research License**" has the meaning set forth in Section 10.2(c).

1.198 [***].

1.199 "**Proteovant Technology**" means, [***].

1.200 "**Proteovant's Knowledge**" means with respect to Proteovant, [***].

1.201 "**Publication**" has the meaning set forth in Section 15.4(a).

1.202 "**Receiving Party**" has the meaning set forth in Section 15.1, subject to the proviso in the definition of Confidential Information.

1.203 "**Reconciliation Report**" has the meaning set forth in Section 11.8(c)(iv).

1.204 "**Registrational Trial**" means, with respect to a Licensed Compound or Licensed Product, a Clinical Trial (whether or not designated a Phase 3 Clinical Trial) that is expected, based on guidance from the FDA or other applicable Regulatory Authority, to provide the basis for submitting an application for Regulatory Approval for such Licensed Compound or Licensed Product (whether it be for the first Regulatory Approval for that Licensed Compound or Licensed Product or expansion of that Regulatory Approval to include an additional Indication for such Licensed Compound or Licensed Product). For the avoidance of doubt, a Clinical Trial or portion thereof may be a Registrational Trial regardless of whether the protocol for such Clinical Trial describes it as a "Phase 1," "Phase 2," or "Phase 3" clinical trial, or any variation thereof.

1.205 "**Regulatory Approval**" means with respect to a country, extra-national territory, province, state, or other regulatory jurisdiction, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell, Manufacture, import, export or market a product in such country, state, province, or some or all of such extra-national territory or regulatory jurisdiction, including any pricing or reimbursement approvals. For the avoidance of doubt, Regulatory Approval includes the approval of a Marketing Authorization Application, and if such approval is received in the U.S. in an expedited manner or in the EU in a conditional manner, such approval is in each case considered a Regulatory Approval for purposes of this definition.

1.206 "**Regulatory Authority**" means, with respect to a particular country, extra-national territory, province, state, or other regulatory jurisdiction, any applicable Governmental Authority with authority over the Development, Manufacture, Regulatory Approval or Commercialization of a Licensed Compound or Licensed Product(s) in or for such country, extra-national territory, province, state, or other regulatory jurisdiction, including the FDA, the EMA and the European Commission, and in each case including any successor thereto.

1.207 "**Regulatory Exclusivity Period**" means, with respect to a Licensed Product in any country or regulatory jurisdiction in the Territory, [***].

1.208 "**Regulatory Materials**" means regulatory applications, submissions, dossiers, drug master files, notifications, registrations, Regulatory Approvals, annual or other periodic reports, or other filings or communications made to or with, or other approvals granted by, a Regulatory Authority in connection with Developing, Manufacturing or Commercializing a Licensed Compound or Licensed Product(s) in a particular country or regulatory jurisdiction. Regulatory Materials include INDs, MAAs and NDAs.

1.209 "**Related Party**" means Blueprint, its Affiliates and its and their respective Sublicensees (and such Sublicensees' Affiliates). For clarity, Related Party will not include any distributors, wholesalers or the like unless such entity is an Affiliate of Blueprint.

1.210 "**Replacement Collaboration Target**" has the meaning set forth in Section 2.4.

1.211 "**Replacement Target Program**" has the meaning set forth in Section 2.4.

1.212 "**Research**" means, with respect to a Collaboration Compound, the conduct of all Nonclinical Studies up until such Collaboration Compound achieves Development Candidate status as set forth in the applicable Research Plan.

1.213 "**Research Milestone Event**" has the meaning set forth in Section 11.3(a).

1.214 "**Research Milestone Payment**" has the meaning set forth in Section 11.3(a).

1.215 "**Research Plan**" has the meaning set forth in Section 2.2(a).

1.216 "**Research Report**" has the meaning set forth in Section 2.8.

1.217 "**Residual Information**" means the Confidential Information disclosed under this Agreement that consists of generalized know-how, or skills gained or learned during the course of each Target Program that are no more than skillful variations of general processes known to the biotechnology and pharmaceutical industries and that is mentally retained in the unaided memories of the receiving Party's and its Affiliates' employees, consultants and subcontractors without making reference to any document or other tangible media containing such Confidential Information.

1.218 "**Response Brief**" has the meaning set forth in Section 19.4(b).

1.219 "**Reversion Compound**" means, with respect to a Terminated Program, the Collaboration Compounds or Licensed Compounds, as applicable, that are the subject of such Terminated Program.

1.220 "**Reversion Product**" means, with respect to a Terminated Program, the Licensed Products, as applicable, that are the subject of such Terminated Program.

1.221 "**Royalty-Bearing Patent**" means, on a Licensed Target Program-by-Licensed Target Program basis any: (a) [***] that Cover the Licensed Compounds or the Licensed Products or [***] the Licensed Compounds or the Licensed Products; and (b) [***] that Cover [***] a Licensed Compound or Licensed Product.

1.222 [***] means, [***].

1.223 "**Royalty Term**" means, on a Licensed Product-by-Licensed Product and country-by-country or region-by-region basis, as applicable, in the Territory, the period starting on the date of the First Commercial Sale of such Licensed Product in such country or region and ending on the latest of: (a) the [***] anniversary of the date of such First Commercial Sale of such Licensed Product in such country or region; (b) expiration of the last-to-expire Valid Claim of the last to expire Royalty-Bearing Patent Covering [***] such Licensed Product in such country or region; and (c) the expiration of the last Regulatory Exclusivity Period for such Licensed Product in such country or region.

1.224 "**Sales Milestone Event**" has the meaning set forth in Section 11.5(a).

1.225 "**Sales Milestone Payment**" has the meaning set forth in Section 11.5(a).

1.226 "**Scheduled Blueprint Contributed Compounds**" means, [***] set forth in the applicable Research Plan for a given Target Program, the Blueprint Target Binder Compounds that Blueprint may elect to list on **Schedule 1.226** with respect to such Target Program.

1.227 "**Scientific Contacts**" means, with respect to a Party, its Chief Scientific Officer or its designee, who has (a) the appropriate expertise in the subject matter for determining whether [***] or [***] will be listed in the Non-Exclusively Licensed Schedule and (b) decision-making authority with respect to such matter.

1.228 [***] means a [***].

1.229 "**SEC**" means the U.S. Securities and Exchange Commission, and any successor agency thereto.

1.230 "**Security Incident**" has the meaning set forth in Section 15.8(b).

1.231 "**Segregated Technology**" has the meaning set forth in Section 20.9(b)(ii).

1.232 "**Sole Know-How**" has the meaning set forth in Section 12.1(a).

1.233 "**Sole Patents**" has the meaning set forth in Section 12.1(a).

1.234 "**Subject Information**" has the meaning set forth in Section 20.9(b)(ii).

1.235 "**Subject Personnel**" has the meaning set forth in Section 20.9(b)(ii).

1.236 "**Sublicensee**" means any Third Party granted a sublicense under Sections 10.1(b), 10.1(c) or 10.1(d) hereof to the rights licensed to Blueprint hereunder, but will not include any Vendor.

1.237 "**Surviving Sublicense**" has the meaning set forth in Section 16.8(a)(i).

1.238 "**Systems**" has the meaning set forth in Section 15.8(a).

1.239 "**Target**" means (a) any specific DNA or protein identified by its ENSEMBL GENE ID number, and (b) if applicable, its genomic mutant identifier.

1.240 "**Target Binder Compounds**" means the compounds that bind directly to a Collaboration Target.

1.241 "**Target Program**" has the meaning set forth in Section 2.1(a).

1.242 "**Target Program Cost Cap**" has the meaning set forth in Section 2.6.

1.243 "**Term**" has the meaning set forth in Section 16.1.

1.244 "**Terminated Program**" has the meaning set forth in Section 16.8.

1.245 "**Terminated Program Materials**" has the meaning set forth in Section 16.8(g)(iii).

1.246 "**Termination Notice**" has the meaning set forth in Section 16.3(a).

1.247 "**Territory**" means all countries of the world.

1.248 "**Third Party**" means any Person other than Proteovant or Blueprint or an Affiliate of either of Proteovant or Blueprint. For purposes of Section 18.2, Third Parties will not include [***].

1.249 "**Third Party Agreements**" means any agreement entered into after the Effective Date between a Third Party and a Party or its Affiliate pursuant to which such Party or its Affiliate gains rights to use such Third Party's Patents or other intellectual property to research, Develop, Manufacture, Commercialize, sell, offer for sale, import, or otherwise Exploit Collaboration Compounds, Licensed Compounds or Licensed Products in the Field in the Territory.

1.250 "**Third Party Payments**" means compensation paid to any Third Party by a Party or by both Parties (or their respective Affiliates) under any Third Party Agreement to the extent attributable to the rights to use such Third Party's Patents or other intellectual property to research, Develop, Manufacture, Commercialize, sell, offer for sale, import, or otherwise Exploit Collaboration Compounds, Licensed Compounds or Licensed Products in the Field in the Territory.

1.251 "**Title 11**" has the meaning set forth in Section 20.3(a).

1.252 "**Transfer Tax**" has the meaning set forth in Section 11.10(d).

1.253 "**U.S.**" means the United States of America and its territories, districts and possessions.

1.254 "**Valid Claim**" means [***].

1.255 "**VantAI**" has the meaning set forth in Section 1.256.

1.256 "**VantAI Agreement**" means [***].

1.257 [***].

1.258 "**Vendor**" means a Third Party engaged by Blueprint or its Affiliates to perform Research, Development, Manufacturing or Commercialization activities on Blueprint's behalf, including without limitation a clinical research organization, contract manufacturing organization, a distributor, a subcontractor, a consultant or any other service provider.

1.259 "**Working Group**" has the meaning set forth in Section 9.7.

2. RESEARCH COLLABORATION OF TARGET PROGRAMS

2.1 Target Programs.

(a) In accordance with the terms of this Agreement, the Parties will collaborate in carrying out a Research Plan with respect to each Collaboration Target to discover and Research Collaboration Compounds (each, a "**Target Program**"). The first Target Program initiated under this Agreement will commence on the Effective Date and the second Target Program initiated under this Agreement will commence no later than [***] after the Effective Date (collectively, the "**Initial Target Programs**"). The Parties will conduct each Initial Target Program in accordance with the applicable Research Plan. Each Party will use Commercially Reasonable Efforts to carry out its respective activities under each Research Plan.

(b) Each Target Program and each Party's performance of its activities under this Agreement will be conducted by each Party in good scientific manner, and in compliance with the requirements of Applicable Law. Each Party will use reasonable efforts to ensure that its Affiliates and Third Party contractors (as applicable) perform any activities under each Target Program in good scientific manner and in compliance with the requirements of Applicable Law.

(c) Each Party agrees to make its relevant employees reasonably available to consult with the other Party on issues that arise in relation to the performance of each Target Program pursuant to the applicable Research Plan.

2.2 Research Plans.

(a) Each Target Program will be carried out in accordance with a mutually agreed upon written Research Plan covering all Research activities up to and including the performance of activities necessary or reasonably useful to determine whether a Collaboration Compound achieves the applicable [***] for nomination as a Development Candidate (each, a "**Research Plan**"). The initial Research Plans for the Initial Target Programs are attached hereto

as **Schedule 2.2(a) – 1** and **Schedule 2.2(a) – 2** . Each Research Plan for each Target Program: (i) will describe the roles and responsibilities of the Parties in support of such Target Program, which roles and responsibilities will be consistent with the roles and responsibilities of the Parties set forth in **Schedule 2.2(a) - 3**, as such roles and responsibilities may be further adjusted and refined by the Parties in the applicable Research Plan; and (ii) will include a description of any milestones and deliverables, the projected timelines for completion of the activities set forth in such Research Plan, provisions for the supply of Collaboration Compounds by Proteovant to Blueprint in accordance with Section 2.9, a copy of the applicable [***] pursuant to which[***], the [***]. Each Research Plan will include plans to develop [***] through to satisfaction of [***]. Each Research Plan will include plans to develop and progress [***], but such Research Plan will not require the Parties to [***].

(b) Each Research Plan will be reviewed by the JRC at least [***] and may, from time to time, be amended by the JRC in accordance with Section 9.2(e), provided that if the JRC decides in accordance with Section 9.2(e) that a Target Program is futile following reasonable efforts to achieve the [***], then such Target Program will be terminated.

(c) For clarity, the conduct of any CMC activities under any Research Plan, other than the Initial Synthesis of the Collaboration Compounds, will be [***].

(d) On a Target Program-by-Target Program basis, prior to achievement of the [***] with respect to such Target Program, [***]; provided, however, that Blueprint will have the right to request [***] 15.

2.3 [***]**.**

(a) Each Research Plan will include the [***], as agreed upon by the Parties.

(b) With respect to each Target Program, the JPT will promptly provide a written report (the "[***]") to the JRC when it believes that [***] has been achieved with respect to a Collaboration Compound and a [***] Candidate has been identified (the "[***]") and will provide to the JRC all material data and other Information in support thereof. [***]. At the time of delivery of the [***] to the JRC, the JPT will request that [***] promptly (but in any event within [***] days of delivery of such request) meet by phone or in person to discuss the [***] with respect to [***]. The JRC will promptly (and in any event within [***] after the date of delivery of the [***] Candidate Report by the JPT (such period, the "[***]")) (i) discuss and evaluate such report and material data and Information (including [***]), (ii) determine whether or not [***] has been achieved and (iii) provide prompt written notice of such determination to each of Proteovant and Blueprint. If the JRC determines, [***], that [***] has been achieved, then [***]11.3 [***] 11.3.

(c) With respect to each Target Program, the JPT will promptly provide a written report (the "[***]") to the JRC when the JPT believes that [***] has been achieved for a Collaboration Compound, and will provide to the JRC all material data and other Information in support thereof. [***]. The JRC will promptly (and in any event within [***] days after the date of delivery of the [***] by the JPT (such period, the "[***]")) (i) discuss and evaluate such report and material data and Information, (ii) determine whether or not [***] has been achieved for a [***] and (iii) provide prompt written notice of such determination to each of Proteovant and

Blueprint. If the JRC determines, [***], that [***] has been achieved for a [***], then [***] 11.3 [***] 11.3.

(d) With respect to each Target Program, the JPT will promptly provide a written report (the "[***]") to the JRC when the JPT believes that a Collaboration Compound has achieved the applicable [***] and will provide to the JRC all material data and other Information in support thereof. [***]. No later than at the time of delivery of the [***] to the JRC, the JPT will request that the [***] meet by phone or in person [***] with respect to such Collaboration Compound. Each Party will have the right to receive a copy of [***]. The JRC will promptly (and in any event within [***] days after the receipt of such [***] by the [***] (such period, the "[***]")) (i) discuss and evaluate such report and material data and Information (including [***]), (ii) determine whether or not the applicable Collaboration Compound has achieved [***] and (iii) provide prompt written notice of such determination to each of Proteovant and Blueprint. If the JRC determines, [***], that such Collaboration Compound achieves [***], then (x) such [***] will be a [***] Candidate and (y) in the event [***] 11.3 [***] 11.3.

(e) From time to time during the [***], and solely to the extent reasonably necessary for the JRC to determine whether the [***], the [***], or the [***] (as applicable) have each been achieved, the JRC may provide to a Party with written notice requesting from such Party reasonable additional information (including, as reasonable, any raw data) with respect to, or the ability to reasonably discuss with such Party's representative(s) who have knowledge of, in each case, the applicable Collaboration Compound (each, an "**Information Request**"). Such Party will [***] provide such information [***] or hold any such discussion [***] after receipt of such Information Request. With respect to any Information Request submitted by a Party during [***] 2.3(b), [***] 2.3(c) [***] 2.3(d), to the extent that (i) [***].

2.4 Replacement Target Program. At any time during the [***] period following the date of commencement of each Initial Target Program as set forth in Section 2.1(a), provided that [***] has not been achieved for the applicable Collaboration Target or, if the JRC determines [***] 9.2(e) [***], the Parties may notify the JRC that they wish to replace such Initial Target Program and the Collaboration Target initially selected for such Target Program (such Target Program, a "**Discontinued Target Program**," and such Collaboration Target, a "**Discontinued Collaboration Target**"), with a replacement Target Program and a replacement Target, provided such Target is an Available Target and is otherwise mutually agreed by the Parties (such Target Program, a "**Replacement Target Program**," and such selected replacement Target, a "**Replacement Collaboration Target**"). Upon receipt of notice by the JRC, the following will apply:

(a) on the date such Target Program is replaced by the mutual written agreement of the Parties and thereafter, neither Party will have any further obligation under the applicable Research Plan with respect to such Discontinued Target Program or Discontinued Collaboration Target and such Discontinued Target Program and Discontinued Collaboration Target will no longer be deemed a Target Program or Collaboration Target, as applicable, under the Agreement;

(b) on the date such Target Program is replaced by mutual agreement of the Parties and thereafter, all licenses granted under this Agreement in connection with the Discontinued Target Program and Discontinued Collaboration Target will immediately terminate;

(c) the Parties will negotiate [***] and [***] mutually agree, within [***] days of such notice, upon a Research Plan for such Replacement Collaboration Target through the JRC [***]; and

(d) if the Parties mutually agree to such Research Plan, then following such agreement the Replacement Target Program and the Replacement Collaboration Target will be deemed to be a Target Program and a Collaboration Target, respectively, subject to the terms and conditions of this Agreement.

[***].

2.5 Additional Targets. At any time prior to the [***] anniversary of the Effective Date, the Parties may mutually agree to expand the collaboration to add up to two (2) additional Target Programs (each, an "**Additional Target Program**") for up to two (2) additional Collaboration Targets (each, an "**Additional Collaboration Target**") by notifying the JRC in writing that they wish to add an Additional Collaboration Target under this Agreement, [***]. If the Parties mutually agree to such Additional Collaboration Target and Research Plan (either through the JRC or otherwise), then following such agreement the Additional Target Program and the Additional Collaboration Target will be deemed to be a Target Program and a Collaboration Target, respectively, subject to the terms and conditions of this Agreement, and Blueprint will pay to Proteovant the Additional Target Program Payment in accordance with Section 11.2.

2.6 Target Program Costs and Expenses. Unless otherwise agreed to by the Parties in writing, each Party will be responsible for all of its expenses incurred in the conduct of its activities under each Target Program; provided that, with respect to such Target Program, (a) unless otherwise agreed to by the Parties in writing, neither Party will be required to incur external costs in connection with any Target Program (including, if applicable a Replacement Target Program for such Target Program) in excess of [***].

2.7 Target Program Records.

(a) Each Party will maintain, and cause its Affiliates and subcontractors to maintain, records of all work conducted in the performance of each Target Program and all results, data, inventions and developments made in the performance of such Target Program, which records will be complete and accurate in all material respects. Such records will be in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

(b) In order to protect the Parties' Patents, under U.S. law, in any patentable inventions conceived or reduced to practice during or as a result of a Target Program, each Party agrees to require its employees and independent contractors to record and maintain all material data and information generated during such Target Program in such a manner as to enable the Parties to use such records to establish the earliest date of invention or diligence the date of reduction to practice. At a minimum, such individuals will record all patentable inventions

generated by them in standard laboratory notebooks (paper or electronic) or other suitable means that are dated and corroborated by non-inventors as necessary.

2.8 Disclosure of Results of Target Program. The JPT will furnish to the JRC, at least at each JRC meeting, an update on the progress under each Research Plan (including with respect to any activities under Section 2.9), including a summary of any material results and data generated by each Party under each Research Plan (the "**Research Report**"). Each Party will provide the JRC with such other information, results and data with respect to the activities under each Research Plan as any member of the JRC may reasonably request that are in a Party's possession or control.

2.9 Materials Transfer.

(a) In order to facilitate the activities under each Target Program, either Party may, at its election, provide to the other Party certain Materials (including (i) supply of Collaboration Compounds, [***] from Proteovant to Blueprint to the extent set forth in the applicable Research Plan, or (ii) supply of Blueprint Target Binder Compounds from Blueprint to Proteovant to the extent set forth in the applicable Research Plan) for use by the other Party in furtherance of the Target Program (in which case the transfer of such Materials will be specified in the applicable Research Plan, **Schedule 1.29**, or the minutes of the JRC). All such Materials (including, as applicable, any progeny, expression products, mutants, replicates, derivatives and modifications thereof that are made by the receiving Party and that include the Materials of the supplying Party), to the extent such Material is not generally available from a Third Party, will be used by the receiving Party in accordance with the terms and conditions of this Agreement solely for purposes of performing its activities under the applicable Research Plan, and the receiving Party will not transfer such Materials (including, as applicable, any progeny, expression products, mutants, replicates, derivatives and modifications thereof) to any Third Party unless to a subcontractor as provided in Section 2.10 or as otherwise expressly contemplated by this Agreement (including the applicable Research Plan), or upon the written consent of the supplying Party, including, as applicable, to any academic, government or research institution. For clarity, this Section 2.9(a) will not restrict either Party from using Materials that are publicly available from a Third Party.

(b) Each Party agrees it will not, and will not attempt to, and will not permit any Affiliate or a Third Party to, or attempt to, identify or determine in any way the chemical, physical or structural characteristics or identity, fragmentation sequence or composition of any of the other Party's Materials nor modify or make derivatives or analogs of the other Party's Materials, including that it will not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of any of the other Party's Materials, including analyzing such Materials by physical, chemical or biochemical means, except, in each case, to the extent set forth in the applicable Research Plan or as necessary to conduct the applicable Research Plan.

(c) Any Materials provided by a Party to the receiving Party (including, as applicable, any progeny, expression products, mutants, replicates, derivatives and modifications thereof) will be used by the receiving Party solely for purposes of conducting the Target Program in accordance with the applicable Research Plan and any unused Materials will be returned to the supplying Party (or destroyed as may be requested by the supplying Party in writing) promptly

following the end of the Term (or the end of the Term to the extent relating to the Target Program or Licensed Target Program, as applicable, to which such Materials relate) or earlier upon request by the supplying Party. All Information that specifically relates to such Materials and such Materials, including in each case any improvements, modifications, and derivatives thereof, will be Confidential Information of the supplying Party. The receiving Party agrees to use all such Materials with prudence and appropriate caution in any experimental work, since all of their characteristics may not be known. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE MATERIALS PROVIDED HEREUNDER ARE EXPERIMENTAL IN NATURE AND ARE PROVIDED "AS IS". EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE SUPPLYING PARTY MAKES NO REPRESENTATIONS, EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EXPRESSLY DISCLAIMS ALL SUCH WARRANTIES, INCLUDING WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE MATERIALS PROVIDED HEREUNDER.

2.10 Subcontracting. Subject to the oversight of the JRC, each Party may subcontract any of the work for which it is responsible in the performance of each Target Program. In the case of any (sub)contracting of Target Program activities by a Party to a Third Party, for any contract entered into after the Effective Date, such Third Party must have entered into a written agreement with such Party that includes terms and conditions protecting and limiting use and disclosure of Materials and Information that are consistent with the obligations under Section 2.9 and Article 15 of this Agreement and that require such Third Party to assign or exclusively license back (with the right to sublicense through multiple tiers) all Intellectual Property Rights with respect to the Collaboration Compounds, Licensed Compounds and Licensed Products developed in the course of performing any such work to such Party consistent with the obligations under Section 12.1; provided, that the term of such Third Party's obligations regarding the use and disclosure of Information will be as long as reasonably negotiated with such Third Party, but in any event no less than [***] after the date of expiration or earlier termination of the applicable subcontract agreement between the subcontracting Party and such Third Party. The (sub)contracting Party is responsible for compliance by such Third Party with the applicable terms and conditions of this Agreement in the same way and to the same extent as such Party.

3. BLUEPRINT OPTIONS

3.1 Option Grant. Proteovant hereby grants Blueprint an exclusive option on a Target Program-by-Target Program basis (each, an "**Option**"), during the Option Exercise Period for the applicable Target Program, exercisable at Blueprint's sole discretion subject to, and in accordance with, Sections 3.2 and Section 3.3, [***] exercise its license rights under Section 10.1 with respect to such Target Program.

3.2 Option Exercise Period. On a Target Program-by-Target Program basis, the "**Option Exercise Period**" for each Target Program will [***] (b) end on the earlier of (i) the [***] day following the date of achievement of the [***] with respect to such Target Program as determined by the JRC in accordance with Section 2.3(d)(ii), (ii) on the date such Target Program is replaced with a Replacement Target Program in accordance with Section 2.4, or (iii) on the date the JRC determines that the [***] for such Target Program is not likely to be achieved and terminates such Target Program.

3.3 Exercise of an Option.

(a) **Exercise**. On a Target Program-by-Target Program basis, Blueprint may exercise an Option, if at all, by delivering an Option Exercise Notice in respect of such Option to Proteovant at any time during the respective Option Exercise Period for such Option. On the applicable Option Exercise Date, [***] and such Target Program and the corresponding Collaboration Compounds will be deemed a "**Licensed Target Program**" and "**Licensed Compounds**" hereunder, respectively. If Blueprint exercises the Option with respect to a particular Target Program prior to the time when the JRC determines, [***], that such Collaboration Compound has achieved [***], then (i) [***], and [***].

(b) **Antitrust Filing**.

(i) On an Option-by-Option basis, not later than the applicable Option Exercise Date with respect to such Option, Blueprint will determine whether any filing or notification is necessary or advisable under any applicable Antitrust Law if Blueprint were to exercise the respective Option pursuant to this Agreement. Proteovant will provide Blueprint with any information (including financial information) reasonably requested by Blueprint for purposes of determining whether a filing or notification under any applicable Antitrust Law is necessary or advisable. Upon the request of Proteovant, Blueprint will share with Proteovant its analysis as to whether any filing or notification is necessary or advisable under any applicable Antitrust Law.

(ii) If Blueprint determines that a filing or notification under any applicable Antitrust Law is necessary or advisable, then Blueprint will indicate the same in the respective Option Exercise Notice for such Option and each of Blueprint and Proteovant will make or cause to be made such notifications and filings as promptly as practicable (but in any event within [***]). [***]. Each Party will use its commercially reasonable efforts to obtain the expiration or termination of the applicable waiting period under the HSR Act, and to obtain the termination or expiration of any other applicable waiting periods or any necessary approvals or consents under any other applicable Antitrust Law, at the earliest possible date after the date of filing. Immediately following the later of the expiration or termination of the last such waiting period, or receipt of any necessary approvals or consents under any other applicable Antitrust Law, Blueprint will send Proteovant written notice that all waiting periods under any applicable Antitrust Law have expired or been terminated and any necessary approvals or consents under any applicable Antitrust Law have been obtained. The effectiveness of the Option Exercise Date for the corresponding Target Program will be deemed to be delayed until the date on which the last waiting period under any applicable Antitrust Law has expired or been terminated or on which the last approval or consent under such Antitrust Law is granted.

(c) **Cooperation**. Each of Blueprint and Proteovant will: (i) reasonably cooperate with each other in connection with any investigation or other inquiry relating to the transactions contemplated by an Option Exercise Notice for an Option; (ii) reasonably keep the other Party informed of any communication received by such Party from, or given by such Party to, the FTC, the DOJ or any other Merger Control Authority and of any communication received or given in connection with any proceeding by a private party, in each case regarding the transactions contemplated by an Option Exercise Notice for an Option; (iii) promptly respond to and certify substantial compliance with any inquiries or requests received from the FTC, the DOJ

or any other Merger Control Authorities for additional information or documentation; (iv) reasonably consult with each other in advance of any meeting or conference with the FTC, the DOJ or any other Merger Control Authority, and to the extent permitted by the FTC, the DOJ or such other Merger Control Authority and reasonably determined by such Party to be appropriate under the circumstances, give the other Parties or their counsel the opportunity to attend and participate in such meetings and conferences; and (v) permit the other Parties or their counsel to the extent reasonably practicable to review in advance, and [***] consider the views of the other Parties or their counsel concerning, any submission, filing or communication (and documents submitted therewith) intended to be given by it to the FTC, the DOJ or any other Merger Control Authority; provided, however, such Party will be under no obligation to reschedule any meetings or conferences with the FTC, the DOJ or any other Merger Control Authority to enable the other Party to attend.

(d) **No Antitrust Undertakings**. Notwithstanding anything to the contrary in Section 3.3(b) through 3.3(e), the term "commercially reasonable efforts" as used in Section 3.3(b) does not require that either Party (i) offer, negotiate, commit to or effect, by consent decree, hold separate order, trust or otherwise, the sale, divestiture, license or other disposition of any capital stock, assets, rights, products or businesses of Blueprint, Proteovant or their respective Affiliates, (ii) agree to any restrictions on the activities of Blueprint, Proteovant or their respective Affiliates, or (iii) pay any material amount or take any other action to prevent, effect the dissolution of, vacate, or lift any decree, order, judgment, injunction, temporary restraining order, or other order in any suit or proceeding that would otherwise have the effect of preventing or delaying any of the transactions contemplated by an Option Exercise Notice for an Option.

(e) **No Effect**. At the election of either Party, immediately upon notice to the other Party, Blueprint's exercise of an Option will become null and void and have no further force or effect if (i) the FTC or DOJ obtains a preliminary injunction against the Parties to enjoin the transactions contemplated by the Option Exercise Notice for such Option or (ii) any applicable waiting periods will not have expired or been terminated, or any necessary approvals or consents will not have been obtained, under any applicable Antitrust Law on or prior to [***] after the effectiveness of the filings and notifications contemplated by Section 3.3(b)(ii). In addition, if the Option Exercise Notice indicates that Blueprint has determined that a notification under applicable Antitrust Law is necessary or advisable, Blueprint will have the right to nullify its exercise of such Option by providing written notice to Proteovant prior to the Option Exercise Date for such Option. Following the voiding or nullification of Blueprint's exercise of an Option for any reason under this Section 3.3(e), the Collaboration Target previously subject to such Option will be treated for all purposes under this Agreement, including Section 3.4, as a Collaboration Target in respect of which Blueprint did not deliver an Option Exercise Notice to Proteovant.

3.4 Option Not Exercised. If Blueprint does not deliver to Proteovant an Option Exercise Notice with respect to a Target Program prior to the expiration of the applicable Option Exercise Period, then Blueprint's Option with respect to such Target Program will expire and this Agreement will terminate with respect to such Target Program in accordance with Section 16.5.

4. PROTEOVANT'S OPT-IN RIGHTS

4.1 Opt-In Right. With respect to the second Target Program and fourth Target Program for which Blueprint exercises the Option, if any (each, an "**Eligible Opt-In Program**"), subject to, and in accordance with, the remainder of this Section 4.1, Blueprint hereby grants to Proteovant during the Opt-In Exercise Period an exclusive option with respect to such Eligible Opt-In Program, exercisable in Proteovant's sole discretion, (a) to jointly Develop in the Territory and jointly Commercialize in the Opt-In Territory such Eligible Opt-In Program and corresponding Licensed Compounds and Licensed Products in accordance with Section 6.3(a) and Section 7.2(b), (b) to share the Shared Development Costs attributable to such Eligible Opt-In Program and corresponding Licensed Compounds and Licensed Products in accordance with Section 11.8(a)(i), and (c) to share the Operating Profits or Losses in the Opt-In Territory for such Eligible Opt-In Program and corresponding Licensed Compounds and Licensed Products in the Opt-In Territory in accordance with Section 11.8(a)(ii), in each case, on the terms set forth in this Agreement (the "**Opt-In Right**").

4.2 Exercise of Opt-In Right. Proteovant may exercise its Opt-In Right with respect to an Eligible Opt-In Program by providing written notice (the "**Opt-In Exercise Notice**") of such exercise to Blueprint at any time during the [***] period immediately following the applicable Blueprint Disclosure Date with respect to the applicable Scheduled Blueprint Contributed Compound that is a [***] for such Eligible Opt-In Program (such period, the "**Opt-In Exercise Period**"). If Proteovant exercises the Opt-In Right with respect to an Eligible Opt-In Program, (a) such Eligible Opt-In Program and corresponding Licensed Compounds and Licensed Products will be deemed an "**Opt-In Target Program**", "**Opt-In Compounds**" and "**Opt-In Products**" hereunder, respectively, (b) the Parties will equally share in the Shared Development Costs for such Opt-In Compounds and Opt-In Products in accordance with Section 11.8(a)(i), and (c) the Parties will equally share in the Operating Profits or Losses in the Opt-In Territory for such Opt-In Compounds and Opt-In Products in accordance with Section 11.8(a)(ii).

5. TECHNOLOGY TRANSITION AFTER OPTION AND OPT-IN EXERCISE

5.1 By Proteovant.

(a) **Initial Transfer**. On a Licensed Target Program-by-Licensed Target Program basis, Proteovant will promptly (but no later than [***]) following the applicable Option Exercise Date for each corresponding Licensed Compound, transfer (which may be through access to a secured electronic database) to Blueprint or its designated Affiliate a copy of tangible embodiments of the Proteovant Know-How and [***] related to such Licensed Compound in its possession and Control as of the Option Exercise Date that Proteovant [***] believes is [***] for the Research, Development, Manufacture, Medical Affairs, Commercialization or other Exploitation of such Licensed Compound, including any documentation (whether held in paper or electronic format) or similar removable media (including e-mails, documents, laboratory notebooks, spreadsheets, copies of standard operating procedures or technical specifications), in each case not previously transferred to Blueprint or its Affiliates under this Agreement.

(b) **Additional Transfers**. Following the initial transfer of Proteovant Know-How and [***] in accordance with Section 5.1(a), in the event that Blueprint or Proteovant [***]

believes tangible embodiments of additional Proteovant Know-How and [***] not previously transferred to Blueprint or its Affiliates under this Agreement is n[***] for the continued Research, Development, Manufacture or Commercialization of such Licensed Compound, Proteovant will transfer (which may be through access to a secured electronic database) to Blueprint a copy of such additional Proteovant Know-How and [***] in Proteovant's possession and Control, including any documentation (whether held in paper or electronic format) or similar removable media (including e-mails, documents, laboratory notebooks, spreadsheets, copies of standard operating procedures or technical specifications).

5.2 By Blueprint.

(a) **Initial Transfer**. On a Licensed Target Program-by-Licensed Target Program basis, if Proteovant exercises its Opt-In Right with respect to such Licensed Target Program, then promptly (but no later than [***] following the applicable Opt-In Exercise Date for the applicable Opt-In Compound, the JPT will meet to discuss and identify the Blueprint Know-How that is necessary or useful for Proteovant to perform the activities assigned to it to in order to Co-Develop and Co-Commercialize such Opt-In Compound. Following the identification of any such Blueprint Know-How by the JPT, Blueprint will [***] (but no later than [***] transfer (which may be through access to a secured electronic database) to Proteovant or its designated Affiliate a copy of tangible embodiments of such Blueprint Know-How in Blueprint's possession and Control, including any documentation (whether held in paper or electronic format) or similar removable media (including e-mails, documents, laboratory notebooks, spreadsheets, copies of standard operating procedures or technical specifications).

(b) **Additional Transfers**. Following the initial transfer of Blueprint Know-How in accordance with Section 5.2(a), in the event that Blueprint or Proteovant determines that tangible embodiments of additional Blueprint Know-How not previously transferred to Proteovant or its Affiliates under this Agreement is [***] for Proteovant to perform the activities assigned for the continued Co-Development or Co-Commercialization of the applicable Opt-In Compound, Blueprint will transfer to Proteovant (which may be through access to a secured electronic database) a copy of such additional Blueprint Know-How in Blueprint's possession and Control, including any documentation (whether held in paper or electronic format) or similar removable media (including e-mails, documents, laboratory notebooks, spreadsheets, copies of standard operating procedures or technical specifications).

5.3 Costs of Transfer. Each Party will bear its own costs and expenses in conducting and receiving the technology transfer under this Article 5.

6. DEVELOPMENT AND REGULATORY MATTERS

6.1 Overview. Subject to the terms and conditions of this Agreement, including Proteovant's exercise of the Opt-In Right in accordance with Article 4, during the Term, on a Licensed Target Program-by-Licensed Target Program basis, from and after the applicable Option Exercise Date, Blueprint, by itself or through its Affiliates and Sublicensees, will be solely responsible for the Development of the Licensed Compounds and Licensed Products under such Licensed Target Program in the Field in the Territory during the Term.

6.2 Development Diligence.

(a) Subject to the terms and conditions of this Agreement, on a Licensed Target Program-by-Licensed Target Program basis Blueprint, by itself or through its Affiliates and Sublicensees, will use Commercially Reasonable Efforts to Develop [***] (including, if applicable, [***] under such Licensed Target Program and to seek and obtain Regulatory Approval for such Licensed Product (including, if appliable, [***]) in the Field [***]. Without limiting the generality of the foregoing, with respect to each Licensed Product that is not an Opt-In Product, Blueprint will prepare [***] and deliver to Proteovant (i) an initial Global Development Plan setting forth Blueprint's plans to meet its obligations under this Section 6.2(a), including [***] relating to [***] activities set forth in such Global Development Plan, and (ii) an updated version of such Global Development Plan on [***] basis thereafter. Blueprint will use Commercially Reasonable Efforts to implement the Global Development Plan.

(b) If Proteovant exercises the Opt-In Right with respect to an Eligible Opt-In Program in accordance with Article 4, then subject to the terms and conditions of this Agreement, each Party will use Commercially Reasonable Efforts to (i) conduct those Development activities with respect to Opt-In Compounds and Opt-In Products in the Field in the Territory allocated to such Party under the Opt-In Global Development Plan, and (ii) carry out the activities assigned to it under the Opt-In Global Development Plan with respect to the Territory, in a timely and effective manner.

6.3 Opt-In Global Development Plan and Opt-In Global Development Budget.

(a) If Proteovant exercises its Opt-In Right with respect to an Eligible Opt-In Program, then during the Opt-In Term:

(i) On an Opt-In Licensed Target Program-by-Opt-In Licensed Target Program basis, subject to the terms and conditions of this Agreement, within [***] days after the Opt-In Exercise Date with respect to such Opt-In Licensed Target Program, Blueprint will prepare [***] and deliver to the JSC for its review, discussion, and approval the initial global Development plan for such Opt-In Licensed Target Program (each, an "**Opt-In Global Development Plan**") which will include: [***] following the delivery of the applicable Opt-In Global Development Plan by Blueprint to the JSC; [***]. In the event of any inconsistency between the Opt-In Global Development Plan and this Agreement, the terms of this Agreement will prevail. Within [***] after the date Blueprint delivers to the JSC the initial Opt-In Global Development Plan as set forth above in this Section 6.3(a)(i), Proteovant will [***]. Third Party subcontractors to be used by either Party to perform activities under the Opt-In Global Development Plan will be selected in a manner intended to maximize efficiencies for the global Development of the Opt-In Compounds and Opt-In Products.

(ii) The Opt-In Global Development Plan will contain a [***] rolling budget for the probable Shared Development Costs for the Development activities to be performed during the then-current Calendar Year [***] and the next [***] of the Opt-In Global Development Plan (each such budget, an "**Opt-In Global Development Budget**"). The first full Calendar Year plus any such partial Calendar Year, if applicable, of the then-current Opt-In Global Development Budget will be binding, and [***] of the Opt-In Global Development Budget will be non-binding.

In addition, the Opt-In Global Development Budget will contain a [***] summary of any foreseeable Shared Development Costs following such [***] rolling budget through the anticipated completion of the last Clinical Trial set forth in the then current Opt-In Global Development Plan.

(iii) Blueprint, in consultation with Proteovant, will (A) review the Opt-In Global Development Plan and Opt-In Global Development Budget at least [***] for the purpose of considering appropriate amendments thereto to be proposed to the JDC for submission to the JSC for approval and (B) no later than [***] of the then-current Calendar Year beginning with the first full Calendar Year of the initial Opt-In Global Development Plan and Opt-In Global Development Budget, provide the JDC with a proposed updated Opt-In Global Development Plan and Opt-In Global Development Budget for the JDC's review, discussion, and submission to the JSC for approval. The JSC will endeavor to approve such updated Opt-In Global Development Plan and Opt-In Global Development Budget no later than [***] of the then current Calendar Year. Each update to the Opt-In Global Development Plan or the Opt-In Global Development Budget will be prepared by the Parties based on each Party's [***] estimation, consistent with its standard internal practices, of the probable activities to be conducted under the Opt-In Global Development Plan, and based on and consistent with the documents and information related to the Opt-In Products prepared by such Party for its internal use.

(iv) During the Opt-In Term, [***] updates to the Opt-In Global Development Budget will contain a proposed Opt-In Global Development Budget covering (A) the next [***],[***], and (B) each of the [***] thereafter, [***], in each case ((A) and (B)), in accordance with the requirements set forth in Section 6.3(a)(ii). The [***] updates to each Opt-In Global Development Budget will further contain any proposed Development activities that were not previously included as Development activities in the then-current Opt-In Global Development Plan and Opt-In Global Development Budget (including studies to support any new Indications). In addition, such [***] updates to the Opt-In Global Development Budget will contain a high-level summary of any foreseeable Shared Development Costs following such updated [***] rolling budget through the anticipated completion of the last Clinical Trial set forth in the then current Opt-In Global Development Plan.

(v) During the Opt-In Term, in addition to the [***] updates, either Party, through its representatives on the JDC, may propose amendments to the Opt-In Global Development Plan and Opt-In Global Development Budget at any time (but no more frequently than [***]) until such time as no further activities are occurring or expected to occur under the Opt-In Global Development Plan and no further costs are expected to be incurred under the Opt-In Global Development Budget, including amendments to add activities to such Opt-In Global Development Plan and Opt-In Global Development Budget (including new Indications). No [***] update or material amendment to an Opt-In Global Development Plan and Opt-In Global Development Budget will be effective unless and until approved by the JSC in accordance with Section 9.4(e).

(b) For clarity, if Proteovant never exercises its Opt-In Right with respect to an Eligible Opt-In Program, then Section 6.3(a) will not apply with respect to such Eligible Opt-In Program and the corresponding Licensed Compounds and Licensed Products.

6.4 Development Reports.

(a) Blueprint will furnish to Proteovant [***] updates on its global Development and regulatory efforts for the Licensed Compounds and Licensed Products that are not Opt-In Compounds or Opt-In Products, including [***].

(b) With respect to each Opt-In Compound and its corresponding Opt-In Products, the JDC will furnish to the JSC, within [***] days after the end of each [***] an update on the global progress of activities under such Opt-In Global Development Plan for such Opt-In Compound and corresponding Opt-In Products, including a summary of any material results and data generated by it in connection with such activities. The JDC will provide the JSC with such other information, results and data with respect to such activities for such Opt-In Compound or corresponding Opt-In Products as any member of the JSC may reasonably request that are in the applicable Party's possession and control to determine such Party's compliance with its Development diligence obligations under this Agreement.

6.5 Development Costs.

(a) Unless and until Proteovant exercises the Opt-In Right with respect to an Eligible Opt-In Program, following the Option Exercise Date, Blueprint will be solely responsible for all costs and expenses incurred in connection with the Development of Licensed Compounds and Licensed Products in the Field in the Territory.

(b) If Proteovant exercises the Opt-In Right with respect to an Eligible Opt-In Program, then from and after the Option Exercise Date for the applicable Licensed Target Program, the Parties will share all Shared Development Costs for all Development activities for such Opt-In Licensed Target Program and the corresponding Opt-In Compounds and Opt-In Products in the Field in the Territory in accordance with the Opt-In Global Development Budget and Section 11.8.

6.6 Records. Each Party will prepare and maintain and will cause its Affiliates, licensees or sublicensees to prepare and maintain records regarding the Development of Licensed Compounds and Licensed Products in the Field in the Territory, which records will be complete and accurate in all material respects and in sufficient detail and good scientific manner appropriate for patent and regulatory purposes.

6.7 Regulatory Matters. As between the Parties, Blueprint will [***] with respect to regulatory matters for Licensed Compounds and Licensed Products, [***] Periods; provided, that if Proteovant exercises its Opt-In Right with respect to an Eligible Opt-In Program, then Blueprint will provide Proteovant with advance copies of any material Regulatory Materials in the Opt-In Territory reasonably in advance of submission to a Regulatory Authority in the Opt-In Territory. Blueprint will consider [***] any reasonable comments by Proteovant to such Regulatory Materials; [***]. Blueprint will have sole responsibility for preparing and submitting all Regulatory Materials for Licensed Products (including the Opt-In Products) in the Field in the Territory, including preparing, submitting and holding all INDs, NDAs and MAAs for such Licensed Products (including the Opt-In Products). Proteovant will reasonably cooperate with Blueprint and provide to Blueprint all Proteovant Know-How and [***], in each case as may be reasonably requested by Blueprint and necessary for Blueprint, in order to prepare or support any Regulatory Materials for Licensed Products (including the Opt-In Products) in the Field in the Territory and interactions with any Regulatory Authority in connection with Development or

Regulatory Approval of Licensed Products (including the Opt-In Products). Blueprint will own all Regulatory Materials for Licensed Products and all such Regulatory Materials will be submitted in the name of Blueprint (or its Affiliate or Sublicensee, as applicable).

6.8 Standards of Conduct. Each Party will perform, and will use Commercially Reasonable Efforts to ensure that its Affiliates, licensees, sublicensees and Third Party contractors perform, its Development activities with respect to Licensed Compounds (including Opt-In Compounds) and Licensed Products (including Opt-In Products) in compliance in all material respects with the requirements of Applicable Law.

6.9 Data Processing Agreement. In the event Proteovant exercises its Opt-In Right in accordance with Article 4, then promptly following the applicable Opt-In Exercise Date, the Parties will [***] negotiate and enter into a Data Processing Agreement.

7. COMMERCIALIZATION

7.1 Overview. Subject to the terms and conditions of this Agreement, including Proteovant's exercise of its Opt-In Right in accordance with Article 4, during the Term, on a Licensed Target Program-by-Licensed Target Program basis, from and after the applicable Option Exercise Date, Blueprint, by itself or through its Affiliates and Sublicensees, will be solely responsible, at its sole cost and expense, for the Commercialization of Licensed Compounds and Licensed Products in the Field in the Territory.

(a) **Commercialization Diligence**.

(i) Subject to the terms and conditions of this Agreement, on a Licensed Target Program-by-Licensed Target Program basis, Blueprint, by itself or through its Affiliates and Sublicensees, will use Commercially Reasonable Efforts to Commercialize [***] Licensed Product (including, [***]) under such Licensed Target Program in the Field [***] Regulatory Approval has been obtained for such Licensed Product.

(ii) If Proteovant exercises the Opt-In Right with respect to an Eligible Opt-In Program in accordance with Article 4, Proteovant will use Commercially Reasonable Efforts to conduct those Co-Commercialization activities with respect to such Opt-In Product in the Opt-In Territory allocated to Proteovant under the applicable Opt-In Commercialization Plan.

7.2 Commercialization of Licensed Products (including Opt-In Products); Commercialization Reports and Records.

(a) With respect to Licensed Products that are not Opt-In Products, on a Licensed Target Program-by-Licensed Target Program basis following [***], Blueprint will deliver to Proteovant a written report summarizing its material Commercialization activities on [***] basis within [***] after [***].

(b) With respect to Opt-In Products in the Opt-In Territory, all Commercialization activities of the Parties will be performed under the direction of the JCC and the JSC in accordance with the then-current applicable Opt-In Commercialization Plan. In the event of any inconsistency between a Opt-In Commercialization Plan or an Operating Budget and

this Agreement, the terms of this Agreement will prevail unless otherwise expressly set forth in the relevant Opt-In Commercialization Plan or Operating Budget.

(c) Each Party will maintain records and otherwise establish procedures to ensure compliance with all Applicable Law and professional requirements that apply to the Commercialization of the Licensed Products and Opt-In Products in the Territory or Opt-In Territory, as applicable.

(d) Blueprint will have the sole right, and will be solely responsible for the invoicing, selling, booking of sales, distribution, market access activities (including listing, tendering, or pricing or reimbursement activities), of each Opt-In Product in the Opt-In Territory.

7.3 Opt-In Commercialization Plan and Operating Budget.

(a) If Proteovant exercises the Opt-In Right with respect to an Eligible Opt-In Program, then:

(i) No later than [***] prior to the expected filing date of the Regulatory Approval for the Opt-In Product in the Opt-In Territory, Blueprint will prepare and submit to the JCC for its review and submission to the JSC for its approval an initial high-level Commercialization plan for the Opt-In Products in the Opt-In Territory (such plan, if and when approved by the JSC and as may be amended from time to time in accordance with this Agreement, the "**Opt-In Commercialization Plan**").

(ii) Each Opt-In Commercialization Plan will contain, as applicable: (A) [***] Commercialization activities for the relevant Opt-In Product in the Opt-In Territory (including without limitation [***], (C) [***] activities, (D) the Parties' respective [***] roles for such Opt-In Product in the Opt-In Territory, (E) [***] for such Opt-In Product, (F) the Operating Budget, [***], and (G) other information the JCC believes necessary for the successful commercial launch and subsequent Commercialization of the applicable Opt-In Product in the Opt-In Territory. Within [***] after the date Blueprint delivers to the JCC the initial Opt-In Commercialization Plan as set forth above in Section 7.3(a)(i), Proteovant will [***]. Blueprint will [***]. Third Party subcontractors to be used by either Party to perform activities under the Opt-In Commercialization Plan will be selected in a manner intended to maximize efficiencies for the Commercialization of the Opt-In Compounds and Opt-In Products in the Opt-In Territory.

7.4 Co-Commercialization Agreement.

(a) On an Opt-In Target Program-by-Opt-In Target Program basis, no later than [***] prior to the [***], the Parties will negotiate [***] the terms of a definitive Co-Commercialization Agreement (the "**Co-Commercialization Agreement**"). The Co-Commercialization Agreement will include terms that are customary in an agreement to govern the Co-Commercialization of similar products in the Opt-In Territory, including agreeing on the scope and split of the Party's Commercialization activities in the Opt-In Territory, and that are otherwise consistent with the provisions of this Agreement. The JCC under the oversight of the JSC will operate as the governing authority for any operations under the Co-Commercialization Agreement. Costs incurred by the Parties for Co-Commercialization activities in the Opt-In Territory under any Co-Commercialization Agreement and in accordance with the Operating

Budget will be Shared Commercialization Costs unless otherwise mutually agreed by the Parties and expressly set forth in the Co-Commercialization Agreement.

(b) In the event the Parties are unable to agree on the terms of a Co-Commercialization Agreement after [***] attempts to reach agreement over a [***] period, then either Party may, by written notice to the other, have such issue referred to the Executive Officers for resolution. If the Executive Officers are unable to resolve the matter within [***], or such other longer time the Executive Officers may otherwise agree upon, after the matter is referred to them, then either Party may refer such issue to arbitration under the expedited dispute resolution provisions in Section 19.4 by providing written notice thereof to the other Party.

8. MANUFACTURING

8.1 Subject to the terms of this Agreement, including Proteovant's exercise of the Opt-In Right in accordance with Section 4.2, following the Option Exercise Date in accordance with Section 3.3, with respect to each Licensed Target Program and corresponding Licensed Compounds and Licensed Products, Blueprint will, [***], have the exclusive right and will be solely responsible for the Manufacture (including having a Third Party Manufacture on its behalf) of such Licensed Compounds and Licensed Products (including all such Manufacturing for use in Clinical Trials and for Commercialization).

8.2 If Proteovant exercises its Opt-In Right with respect to an Eligible Opt-In Program in accordance with Section 4.2, then Blueprint will continue to have the exclusive right and to be solely responsible for the Manufacture (including having a Third Party Manufacture on its behalf) of the Opt-In Compounds and Opt-In Products (including all such Manufacturing for use in Clinical Trials and for Commercialization); provided, however, that [***] 11.8.

9. GOVERNANCE

9.1 Collaboration Overview. The Parties desire and intend to work together leveraging each Party's expertise to collaborate with respect to the Target Programs, as and to the extent set forth in this Agreement (the "**Collaboration**"). The Parties will establish a governance structure to oversee and govern the Collaboration.

9.2 Joint Research Committee.

(a) **Establishment of JRC**. Within [***] after the Effective Date, the Parties will establish a joint research committee to oversee solely the Research of the Target Programs with the roles set forth in Section 9.2(c) (the "**Joint Research Committee**" or "**JRC**"). The JRC will consist at all times of an equal number of representatives of each of Proteovant and Blueprint. Each Party will initially appoint three (3) representatives to the JRC. The JRC membership and procedures are further described in this Section 9.2. Each Party may at any time appoint different JRC representatives by written notice to the other Party.

(b) **Membership of JRC**. Each of Proteovant and Blueprint will designate representatives with appropriate expertise to serve as members of the JRC, all of whom will have sufficient seniority within the applicable Party to make decisions arising within the scope of the JRC's responsibilities as appropriate to optimize the efficiency and speed of the Parties' activities

under this Agreement and the probability of success of each Target Program. The JRC will be chaired by one of the representatives ("**JRC Chairperson**") and will rotate between the Parties every [***] during the Term. The initial JRC Chairperson will be a representative of [***], and a [***] representative will become the Chairperson of the JRC for the next [***] period during the Term. The JRC Chairperson, with assistance and guidance from the Alliance Managers, will be responsible for calling meetings and preparing and circulating an agenda in advance of each meeting, provided that the JRC Chairperson will call a meeting of the JRC promptly upon the reasonable written request of any member of the JRC to convene such a meeting. The role of the JRC Chairperson will be to convene and preside at meetings of the JRC and to ensure that the Alliance Managers prepare minutes, but the JRC Chairperson will have no additional powers or rights beyond those held by the other JRC representatives. The employees or consultants of a Party who are not representatives of such Party on the JRC may attend meetings of the JRC with, with respect to consultants, the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed; provided, however, that such attendees (i) will not vote or otherwise participate in the decision-making process of the JRC and (ii) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 15.

(c) **Role of JRC**. The JRC will be responsible for:

(i) overseeing the progress of Research for the Target Programs under the Research Plans and the activities of the JPTs,

(ii) providing guidance on overall strategy, priorities, and decisions for each Target Program up until the Collaboration Compound achieves [***] as set forth in the applicable Research Plan,

(iii) serving as a forum for exchanging information and facilitating discussions regarding the conduct of each Target Program,

(iv) reviewing and approving amendments to the Research Plans,

(v) reviewing and discussing Research Reports prepared by the JPT in accordance with Section 2.8,

(vi) ensuring that Research for each Target Program remains on track according to terms and goals in this Agreement and the applicable Research Plan,

(vii) discussing and reviewing the [***] and material data and Information provided by the JPT to the JRC in accordance with Section 2.3(b),

(viii) discussing and reviewing the [***] and material data and Information provided by the JPT to the JRC in accordance with Section 2.3(c),

(ix) discussing and reviewing the [***] and material data and Information provided by the JPT to the JRC in accordance with Section 2.3(d),

(x) evaluating and determining whether [***] have been achieved in accordance with Section 2.3(b), Section 2.3(c) and Section 2.3(d),

(xi) reviewing each Progress Update provided by Blueprint in accordance with Section 14.1(b), if applicable,

(xii) monitoring each Party's progress against the Target Program Cost Cap,

(xiii) attempting to resolve issues on matters within the JRC's authority on an informal basis and [***] prior to the institution of escalation or other formal dispute resolution mechanisms hereunder, and

(xiv) carrying out such other responsibilities as expressly delegated to the JRC as set forth in this Agreement or as may be mutually agreed by the Parties from time to time or establishing other Committees to perform such other functions as appropriate.

For the avoidance of doubt, following the Option Exercise Date for the relevant Target Program (unless otherwise expressly contemplated by this Agreement) and completion of the activities under the Research Plan for such Target Program, the JRC will have no oversight, control or authority with respect to the applicable Licensed Target Program.

(d) **JRC Meetings**. The JRC will hold meetings at such times and places as the JRC Chairperson may determine. With respect to each Target Program, the JRC will meet at least once every Calendar Quarter until the earliest of: (i) if Blueprint exercises the Option for such Target Program, [***] (ii) if Blueprint does not exercise the Option for such Target Program, the last day of the Option Exercise Period for such Target Program; and (iii) the date such Target Program is terminated in accordance with this Agreement. The meetings of the JRC may be by telephone or any other method determined by the JRC; provided that there will be an in person meeting at least [***] unless the Parties agree otherwise. Each Party will bear its own costs associated with attending such meetings, including any costs relating to travel or such Party's participation in such meetings.

(e) **Decisions of the JRC**. Decisions of the JRC will be by unanimous vote, with each Party having collectively one (1) vote, provided that if, after attempts to amicably resolve any disagreement at the JRC, the Parties are unable to agree on a matter to be decided by the JRC within [***] after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue referred to the Executive Officers for resolution in accordance with Section 19.2. If the Executive Officers are unable to resolve the matter within [***], or such other longer time the Executive Officers may otherwise agree upon, after the matter is referred to them, then such matter will be resolved in accordance with Section 19.2; provided, however, that [***] 2.3(b), [***] 2.3(c) [***] 2.3(d). For clarity, notwithstanding anything to the contrary, neither Party will have final decision-making authority (*i.e.*, consensus will be required) with respect to any disagreements related to:

(i) [***];

(ii) [***];

(iii) [***];

(iv) [***];

(v) [***]; or

(vi) other matters customarily not delegated to a Party, such as the right to amend the Agreement, or to determine whether the Agreement has been breached or required a Party to violate Applicable Law.

9.3 Joint Project Team.

(a) **Establishment of JPT**. [***] after the Effective Date, the JRC will establish a joint project team (the "**Joint Project Team**" or "**JPT**") for each Target Program to oversee and execute activities under the applicable Research Plan for such Target Program. The JPT will consist at all times of an equal number of representatives of each of Proteovant and Blueprint. Each Party will initially appoint three (3) representatives to the JPT. The JPT membership and procedures are further described in this Section 9.3. Each Party may at any time appoint different JPT representatives by written notice to the other Party.

(b) **Membership of JPT**. Each of Proteovant and Blueprint will designate in writing, in its sole discretion, three (3) representatives with appropriate expertise and ongoing familiarity with each applicable Target Program and Research Plan and sufficient authority to make binding decisions with respect to the applicable Target Program on behalf of the Parties to serve as members of the JPT. The JPT will be chaired by one of the representatives ("**JPT Chairperson**") and will rotate between the Parties every [***] during the Term. The initial JPT Chairperson will be a representative of [***], and a [***] representative will become the Chairperson of the JPT for the following [***] period during the Term. The JPT Chairperson will be responsible for calling meetings and preparing and circulating an agenda in advance of each meeting, provided that the JPT Chairperson will call a meeting of the JPT promptly upon the reasonable written request of any member of the JPT to convene such a meeting. The role of the JPT Chairperson will be to convene and preside at meetings of the JPT, but the JPT Chairperson will have no additional powers or rights beyond those held by the other JPT representatives. Each Party may invite representatives, employees, or other consultants of such Party or of its Affiliates to attend any meeting of the JPT as it determines is appropriate, with the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed; provided, however, that such attendees (i) will not vote or otherwise participate in the decision-making process of the JPT, and (ii) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 15 of this Agreement.

(c) **Role of JPT**. The JPT will be responsible for:

(i) overseeing the progress of the applicable Research Plan,

(ii) reviewing and assessing data collected under the applicable Target Program,

(iii) preparing and presenting to the JRC the [***],

(iv) discussing assay development,

(v) discussing compound activity and design related to such activity,

(vi) discussing next step plans and timelines with respect to the applicable Target Program,

(vii) discussing and identifying any Blueprint Know-How that Blueprint will transfer to Proteovant in accordance with Section 5.2(a), and

(viii) carrying out such other responsibilities as expressly delegated to the JPT as set forth in this Agreement or as may be mutually agreed by the Parties in writing from time to time.

At each meeting of the JPT, if applicable, each Party will summarize to the JPT the progress conducted pursuant to the Research Plan for the applicable Target Program, with each summary including all material decisions and actions and summaries of data generated since the prior JPT meeting.

(d) **JPT Meetings**. The JPT will meet at least [***] until the earliest of: (i) if Blueprint exercises the Option for such Target Program, [***]; (ii) if Blueprint does not exercise the Option for such Target Program, the last day of the Option Exercise Period for such Target Program; and (iii) the date such Target Program is terminated in accordance with this Agreement. The meetings of the JPT may be by telephone or any other method determined by the JPT; provided that there will be an in person meeting at least [***] unless the Parties agree otherwise. Each Party will bear its own costs associated with attending such meetings, including any costs relating to travel or such Party's participation in such meetings. A quorum of the JPT will exist whenever there is present at a meeting at least [***] representatives appointed by each Party. The Parties acknowledge and agree that, notwithstanding the requirements of this Section 9.2 for the JPT to meet at least [***], the Parties will communicate and meet (as appropriate) on a more informal basis as needed to discuss the implementation of Research Plans or needs of Target Programs. The JPT Chairperson or their designees will keep minutes of each JPT meeting that record in writing any actions, decisions or determinations approved by the JPT and any other appropriate matters, including a list of any issues to be resolved by the Executive Officers.

(e) **Decisions of the JPT**. Decisions of the JPT will be by unanimous vote, with each Party having collectively one (1) vote, provided that if, after attempts to amicably resolve any disagreement at the JPT, the Parties are unable to agree on a matter to be decided by the JPT within [***] after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue referred to the JRC for resolution in accordance with Section 9.2(e).

9.4 Joint Steering Committee following Exercise of Proteovant Opt-In Right.

(a) **Establishment of JSC**. Promptly but in no event later than [***] after Proteovant's exercise of its Opt-In Right in accordance with Article 4, the Parties will establish a joint steering committee to act as a forum to review, discuss and oversee activities under this

Agreement related to the Development and Manufacture in the Territory and Commercialization in the Opt-In Territory of the Opt-In Compounds and the Opt-In Products as set forth herein (the "**Joint Steering Committee**" or "**JSC**"). The JSC will consist at all times of an equal number of representatives of each of Proteovant and Blueprint. Each Party will initially appoint three (3) representatives to the JSC. The JSC membership and procedures are further described in this Section 9.4. Each Party may at any time appoint different JSC representatives by written notice to the other Party.

(b) **Membership of JSC**. Each of Proteovant and Blueprint will designate representatives with appropriate expertise and ongoing familiarity with the Opt-In Compounds and the Opt-In Products to serve as members of the JSC. Each of Proteovant and Blueprint will select from their representatives a co-chairperson for the JSC, and each Party may change its designated chairperson from time to time upon written notice to the other Party. The co-chairpersons, with assistance and guidance from the Alliance Managers, will be responsible for calling meetings and preparing and circulating an agenda in advance of each meeting, provided that the co-chairpersons will call a meeting of the JSC promptly upon the reasonable written request of either co-chairperson to convene such a meeting. The role of the co-chairpersons will be to convene and preside at meetings of the JSC and to ensure that the Alliance Managers prepare minutes, but the co-chairpersons will have no additional powers or rights beyond those held by the other JSC representatives. Employees or consultants of a Party who are not representatives of such Party on the JSC may attend meetings of the JSC with the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed; provided, however, that such attendees (i) will not vote or otherwise participate in the decision-making process of the JSC and (ii) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 15.

(c) **Role of JSC**. In addition to its overall responsibility for monitoring and providing a forum to discuss and oversee the Parties' activities under this Agreement with respect to the Opt-In Licensed Target Program, the JSC will be responsible for:

(i) facilitating the flow of information between the Parties with respect to the Opt-In Compounds and the Opt-In Products,

(ii) reviewing and discussing reports from the JDC and JCC and providing guidance thereto and directing activities of the JDC and JCC,

(iii) during the Opt-In Term, reviewing, discussing and approving the initial Opt-In Global Development Plan (including the initial Opt-In Global Development Budget) submitted by Blueprint in accordance with Section 6.3(a)(i),

(iv) reviewing, discussing and approving amendments to the Opt-In Global Development Plan (including the Opt-In Global Development Budget) submitted by the JDC in accordance with Section 9.5(c)(ii),

(v) reviewing, discussing and approving the initial Opt-In Commercialization Plan and Operating Budget and any amendments thereto submitted by the JCC in accordance with Section 9.6(c),

(vi) monitoring and serving as a forum for discussing strategies for obtaining Regulatory Approvals for Opt-In Compounds and the Opt-In Products in the Field and in the Opt-In Territory,

(vii) attempting to resolve issues presented to it by, and disputes within the JDC or the JCC, as applicable, and

(viii) carrying out such other responsibilities as expressly delegated to the JSC as set forth in this Agreement or as may be mutually agreed by the Parties from time to time.

As needed, the JSC will establish Working Groups in accordance with Section 9.7 that will report to the JSC to further the objectives and intent of this Agreement.

(d) **JSC Meetings**. The JSC will hold meetings at such times and places as the co-chairpersons may determine. The JSC will meet at least [***] during the Opt-In Term with respect to an Opt-In Product. The meetings of the JSC may be by telephone or any other method determined by the JSC; provided that there will be an in person meeting at least [***]. Each Party will bear its own costs associated with attending such meetings, including any costs relating to travel or such Party's participation in such meetings.

(e) **Decisions of the JSC**. Decisions of the JSC will be by unanimous vote, with each Party having collectively one (1) vote, provided that if, after attempts to amicably resolve any disagreement at the JSC, the Parties are unable to agree on a matter to be decided by the JSC within [***] after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue referred to the Executive Officers for resolution in accordance with Section 19.2. If the Executive Officers are unable to resolve the matter within [***], or such other longer time the Executive Officers may otherwise agree upon, after the matter is referred to them, [***], subject to the exceptions set forth in clauses (i) through (iii) of this Section 9.4(e):

(i) [***] (A) with respect to [***] [***], or (B) [***]; and

(ii) [***] will not use its [***] to:

(A) require [***] to violate any Applicable Law,

(B) amend the terms and conditions of this Agreement, or

(C) approve any amendment, revision, or update to the Opt-In Global Development Budget or Operating Budget other than in accordance with Section 9.4(e)(i).

(f) For clarity, (i) with respect to a Licensed Compound or a Licensed Product that is not an Opt-In Compound or Opt-In Product, Blueprint will [***] over [***].

9.5 Joint Development Committee following Exercise of Proteovant Opt-In Right.

(a) **Establishment of JDC.** Promptly but in no event later than [***] after Proteovant's exercise of its Opt-In Right in accordance with Article 4, the Parties will establish a committee to act as a forum to review, discuss and oversee Development (including

Manufacturing) of Opt-In Products in the Field in the Territory with the roles set forth in Section 9.5(c) (the "**Joint Development Committee**" or "**JDC**"). The JDC will consist at all times of an equal number of representatives of each of Proteovant and Blueprint. Each Party will initially appoint three (3) representatives to the JDC. The JDC membership and procedures are further described in this Section 9.5. Each Party may at any time appoint different JDC representatives by written notice to the other Party.

(b) **Membership of JDC**. Each of Proteovant and Blueprint will designate representatives with appropriate expertise in the development of products similar to the Opt-In Products to serve as members of the JDC. Each of Proteovant and Blueprint will select from their representatives a co-chairperson for the JDC, and each Party may change its designated co-chairperson from time to time upon written notice to the other Party. The Alliance Managers will be responsible for calling meetings and preparing and circulating an agenda in advance of each meeting, provided that the co-chairpersons will call a meeting of the JDC promptly upon the reasonable written request of either co-chairperson to convene such a meeting. The role of the co-chairpersons will be to convene and preside at meetings of the JDC and to ensure that the Alliance Managers prepare minutes, but the co-chairpersons will have no additional powers or rights beyond those held by the other JDC representatives. Employees or consultants of a Party who are not representatives of such Party on the JDC may attend meetings of the JDC with the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed; provided, however, that such attendees (i) will not vote or otherwise participate in the decision-making process of the JDC and (ii) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 15.

(c) **Role of JDC**. The JDC will be responsible for:

(i) the overall management of the Development of Opt-In Products in the Field in the Territory under the oversight of the JSC,

(ii) during the Opt-In Term, reviewing and approving for submission to the JSC any amendments to the Opt-In Global Development Plan (including the Opt-In Global Development Budget) submitted by the Parties in accordance with Section 6.3(a)(iii) and 6.3(a)(v),

(iii) discussing and coordinating Medical Affairs activities in support of the Development of Opt-In Products in accordance with the Opt-In Global Development Plan,

(iv) discussing and coordinating activities in support of the development of a CDx, if applicable, in accordance with the Opt-In Global Development Plan, and

(v) carrying out such other responsibilities as expressly delegated to the JDC as set forth in this Agreement or as may be mutually agreed by the Parties from time to time.

As needed, the JDC will establish Working Groups in accordance with Section 9.7 that will report to the JDC to further the objectives and intent of this Agreement.

(d) **JDC Meetings**. The JDC will hold meetings at such times and places as the co-chairpersons may determine. The JDC will meet at least [***] during the Opt-In Term for an Opt-In Product. The meetings of the JDC may be by telephone or any other method determined by

the JDC; provided that there will be an in person meeting at least [***] unless the Parties agree otherwise. Each Party will bear its own costs associated with attending such meetings, including any costs relating to travel or such Party's participation in such meetings.

(e) **Decisions of the JDC**. Decisions of the JDC will be by unanimous vote, with each Party having collectively one (1) vote, provided that if, after attempts to amicably resolve any disagreement at the JDC, the Parties are unable to agree on a matter to be decided by the JDC within [***] after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue referred to the JSC for resolution in accordance with Section 9.4(e).

9.6 Joint Commercialization Committee following Exercise of Proteovant Opt-In Right.

(a) **Establishment of JCC**. No later than [***], the Parties will establish a committee to oversee Commercialization of Opt-In Products in the Opt-In Territory with the roles set forth in Section 9.6(e) and as may be further set forth in the Co-Commercialization Agreement (the "**Joint Commercialization Committee**" or "**JCC**"). The JCC will consist at all times of an equal number of representatives of each of Proteovant and Blueprint. Each Party will initially appoint three (3) representatives to the JCC. The JCC membership and procedures are further described in this Section 9.6. Each Party may at any time appoint different JCC representatives by written notice to the other Party.

(b) **Membership of JCC**. Each of Proteovant and Blueprint will designate representatives with appropriate expertise in the commercialization of products similar to the Opt-In Product to serve as members of the JCC. Each of Proteovant and Blueprint will select from their representatives a co-chairperson for the JCC, and each Party may change its designated co-chairperson from time to time upon written notice to the other Party. The Alliance Managers will be responsible for calling meetings and preparing and circulating an agenda in advance of each meeting, provided that the co-chairpersons will call a meeting of the JCC promptly upon the reasonable written request of either co-chairperson to convene such a meeting. The role of the co-chairpersons will be to convene and preside at meetings of the JCC and to ensure that the Alliance Managers prepare minutes, but the co-chairpersons will have no additional powers or rights beyond those held by the other JCC representatives. Employees or consultants of a Party who are not representatives of such Party on the JCC may attend meetings of the JCC with the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed; provided, however, that such attendees (i) will not vote or otherwise participate in the decision-making process of the JCC and (ii) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 15.

(c) **Role of JCC**. The JCC will be responsible for:

(i) the overall management of the Commercialization activities in the Field in the Opt-In Territory for Opt-In Products (including the activities conducted under the Co-Commercialization Agreement, if any),

(ii) subject to Section 7.4, resolving disagreements during the course of implementing the Co-Commercialization Agreement, if any,

(iii) reviewing and approving for submission to the JSC the initial Opt-In Commercialization Plan and Operating Budget and any amendments thereto submitted by the Parties in accordance with Section 7.3(a)(i),

(iv) discussing and coordinating Medical Affairs activities in support of the Commercialization of Opt-In Products in the Opt-In Territory in accordance with the Opt-In Commercialization Plan, and

(v) carrying out such other responsibilities as expressly delegated to the JCC as set forth in this Agreement or as may be mutually agreed by the Parties from time to time.

As needed, the JCC will establish Working Groups in accordance with Section 9.7 that will report to the JCC to further the objectives and intent of this Agreement.

(d) **JCC Meetings**. The JCC will hold meetings at such times and places as the co-chairpersons may determine. The JCC will meet at least [***] during the Opt-In Term for an Opt-In Product. The meetings of the JCC may be by telephone or any other method determined by the JCC; provided that there will be an in person meeting at least [***] unless the Parties agree otherwise. Each Party will bear its own costs associated with attending such meetings, including any costs relating to travel or such Party's participation in such meetings.

(e) **Decisions of the JCC**. Decisions of the JCC will be by unanimous vote, with each Party having collectively one (1) vote, provided that if, after attempts to amicably resolve any disagreement at the JCC, the Parties are unable to agree on a matter to be decided by the JCC within [***] after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue referred to the JSC for resolution in accordance with Section 9.4(e).

9.7 Subcommittees and Working Groups following Exercise of Proteovant Opt-In Right. From time to time, the JSC, JDC, and JCC (each, a "**Committee**") may establish and delegate duties to other committees, subcommittees or directed teams, including a joint Medical Affairs committee to ensure compliance with Applicable Law (each, a "**Working Group**") on an "as needed" basis to oversee particular projects or activities which delegations will be reflected in the minutes of the meetings of the respective Committee. Such Working Groups may be established on an ad hoc basis for purposes of a specific project, or on such other basis as the respective Committee may determine, and will be constituted and will operate as such Committee may determine. Each Working Group and its activities will be subject to the direction, review and approval of, and will report to, the respective Committee. In no event will the authority of the Working Group exceed that specified for the Committees in this Article 9. Any matter not resolved by a Working Group will be referred to the respective Committee for resolution in accordance with Section 9.2(e), Section 9.4(e), Section 9.5(e) or Section 9.6(e) as applicable.

9.8 Discontinuation of Committees. Unless otherwise agreed to by the Parties, on a Target Program-by-Target Program basis, the JRC and each JPT will automatically discontinue upon the earliest of: (i) if Blueprint exercises the Option for such Target Program, [***]; (ii) if

Blueprint does not exercise the Option for such Target Program, the last day of the Option Exercise Period for such Target Program; and (iii) the date such Target Program is terminated in accordance with this Agreement. The JSC will continue to exist until the end of the last-to-expire Opt-In Term of any Opt-In Product. The JDC will continue to exist until the Parties agree it will discontinue but not longer than the end of the last-to-expire Opt-In Term of any Opt-In Product. The JCC will continue to exist until the date on which neither Blueprint nor Proteovant are Commercializing an Opt-In Product. Thereafter, the discontinued Committee will have no further roles or responsibilities under this Agreement, and such Committee will be replaced by designees of each Party (who may be the Alliance Manager) that will serve as a forum for the Parties for the purposes of the exchange of information relating to Licensed Compounds (including, for, clarity, Opt-In Compounds) and Licensed Products (including, for clarity, Opt-In Products).

9.9 Limitations on Authority of the Committees. Each Committee will have solely the roles and responsibilities assigned to it in this Article 9 or the Co-Commercialization Agreement, if any. Notwithstanding Section 9.2(e), Section 9.3(e), Section 9.4(e), Section 9.5(e) or Section 9.6(e), no Committee will have any authority to amend, modify or waive compliance with this Agreement. No Committee will have any authority to alter, or waive compliance by a Party with, a Party's obligations under this Agreement. No Committee or Party in exercising its final decision-making authority under this Article 9 will have any authority to make any decision that expressly requires mutual agreement of the Parties or the consent of a Party.

9.10 Minutes. The Alliance Managers will be responsible for preparing and circulating reasonably detailed written minutes of each meeting of the Committees, setting forth, inter alia, the meeting attendees, an overview of the discussions at the meeting and a list of any actions, decisions or determinations approved by the respective Committee. Such minutes will be effective only after such minutes have been approved by both Parties in writing. Definitive minutes of all Committee meetings will be finalized no later than [***] after the meeting to which the minutes pertain.

9.11 Alliance Managers. Each of the Parties will appoint one (1) representative whose role is to act as a primary point of contact between the Parties to assure a successful relationship between the Parties (each, an "**Alliance Manager**"). The Alliance Managers will attend all meetings of each of the Committees and Working Groups and support the co-chairpersons of such Committees in the discharge of their responsibilities; provided, however, that the Alliance Managers will not vote or otherwise participate in the decision-making process of the JRC, JSC, JDC, JCC or any other Committee. An Alliance Manager may bring any matter to the attention of the applicable Committee(s) if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of such Alliance Manager upon written notice to the other Party's Alliance Manager. Each Alliance Manager will be charged with creating and maintaining a collaborative work environment within each Committee. Each Alliance Manager also will:

(a) provide a primary point of contact both internally within the Parties' respective organizations and between the Parties, including during such time as any of the Committees is no longer constituted,

(b) plan and coordinate any cooperative efforts under this Agreement, if any, and internal and external communications,

(c) take responsibility for ensuring that the activities of each of the Committees, such as the conduct of required meetings of such Committees, occur as set forth in this Agreement and that relevant action items, if any, resulting from such meetings are appropriately carried out or otherwise addressed, and

(d) be the point of first referral in all matters of conflict resolution.

10. GRANT OF RIGHTS AND LICENSES

10.1 Licenses to Blueprint. Subject to the terms and conditions of this Agreement, Proteovant hereby grants to Blueprint:

(a) a non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees as provided in Section 10.5, under the Proteovant Technology solely to the extent necessary for Blueprint to conduct its activities under the Research Plans;

(b) on a Licensed Target Program-by-Licensed Target Program basis, an exclusive (even as to Proteovant) license, with the right to grant sublicenses through multiple tiers of sublicensees as provided in Section 10.5, under the Proteovant Know-How, Proteovant Patents and Proteovant's interests in Joint Know-How and Joint Patents, to Research, Develop, Manufacture, Commercialize and otherwise Exploit Licensed Compounds and Licensed Products (including to perform Medical Affairs activities in support thereof) in the Field in the Territory; provided that in the event Proteovant exercises its Opt-In Right with respect to an Eligible Opt-In Program, then with respect to such Eligible Opt-In Program such license will convert to a co-exclusive (with Proteovant) license during the Opt-In Term in accordance with Section 10.2(b);

(c) on a Licensed Target Program-by-Licensed Target Program basis, an exclusive license (even as to Proteovant, subject to the Proteovant Research License), with the right to grant sublicenses through multiple tiers of sublicensees as provided in Section 10.5, to the [***] and under the [***], in each case, that [***] relate to Licensed Compounds or Licensed Products directed to the Collaboration Target (collectively, the "[***]"), to Research, Develop, Manufacture, Commercialize and otherwise Exploit Licensed Compounds and Licensed Products (including to perform Medical Affairs activities in support thereof) in the Field in the Territory; provided, that in the event Proteovant exercises its Opt-In Right with respect to an Eligible Opt-In Program, then with respect to such Eligible Opt-In Program such license will convert to a co-exclusive (with Proteovant, subject to the Proteovant Research License) license during the Opt-In Term in accordance with Section 10.2(b); and

(d) on a Licensed Target Program-by-Licensed Target Program basis, a non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees as provided under Section 10.5, to the [***] and under the [***] Patents, in each case, other than the Exclusively Licensed [***] Technology (the "**Non-Exclusively Licensed** [***]"), to Research, Develop, Manufacture, Commercialize and otherwise Exploit Licensed Compounds and Licensed Products (including to perform Medical Affairs activities in support thereof) in the Field in the Territory.

10.2 Licenses to Proteovant. Subject to the terms and conditions of this Agreement, Blueprint hereby grants to Proteovant:

(a) a non-exclusive license, with the right to grant sublicenses through multiple tiers of sublicensees as provided in Section 10.5, under the Blueprint Technology solely to the extent necessary for Proteovant to conduct its activities under the Research Plans;

(b) following Proteovant's exercise of the Opt-In Right: (i) a co-exclusive (with Blueprint) license, with the right to grant sublicenses through multiple tiers of sublicensees as provided in Section 10.5, under the Blueprint Technology, the Product Patents, and Blueprint's interests in Joint Know-How and Joint Patents, to Co-Develop the Opt-In Compounds and Opt-In Products in the Territory in accordance with the Opt-In Global Development Plan; and (ii) a co-exclusive (with Blueprint) license, with the right to grant sublicenses through multiple tiers of sublicensees as provided in Section 10.5, under the Blueprint Technology, the Product Patents and Blueprint's interests in Joint Know-How and Joint Patents, to Co-Commercialize the Opt-In Compounds and Opt-In Products in the Opt-In Territory in accordance with the Opt-In Commercialization Plan; and

(c) [***].

10.3 [***].

10.4 Restrictive Covenants. Blueprint will not exercise any rights granted to it under Sections 10.1(b), 10.1(c) and 10.1(d), unless and until (a) on a Target Program-by-Target Program basis, [***] with respect to such Target Program in accordance with Section 3.3, or (b) this Agreement is rejected by or on behalf of Proteovant pursuant to Title 11 or is repudiated by or on behalf of Proteovant under Title 11 or other Applicable Law.

10.5 Sublicensing.

(a) Each Party will have the right to sublicense, through multiple tiers, the licenses granted to it by the other Party under Section 10.1(a) or Section 10.2(a), as applicable, to (i) [***].

(b) Blueprint will have the right to sublicense, through multiple tiers, [***].

(c) Proteovant will have the right to sublicense, through multiple tiers, the license granted to it under Section 10.2(b) to: (i) its Affiliates; and (ii) to the Third Party subcontractors [***].

(d) Each Party will be responsible for the performance of any of its sublicensees (including Sublicensees, with respect to Blueprint) that are exercising rights under a sublicense of the licenses granted to such Party hereunder, and the grant of any such sublicense will not relieve such sublicensing Party of its obligations under this Agreement, except to the extent they are satisfactorily performed by any such sublicensee(s) (including Sublicensees, with respect to Blueprint). Each sublicense agreement with a sublicensee (including a Sublicensee, with respect to Blueprint) under this Agreement will be subject to the applicable terms and conditions of this Agreement. [***].

10.6 No Other Rights. Except for the licenses and rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by a Party to the other Party. All rights with respect to Information, Patents or other Intellectual Property Rights that are not specifically granted herein are reserved to the owner thereof. Neither Party nor any of its Affiliates will use or practice any Information or Patents licensed or provided to such Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.

11. PAYMENTS

11.1 Upfront Payment. Blueprint will pay Proteovant an upfront payment in the amount of twenty million Dollars ($20,000,000) no later than [***] after the Effective Date. Such payment will be non-creditable and non-refundable.

11.2 Fee for Additional Target Program. Blueprint will pay Proteovant a non-refundable, non-creditable payment in the amount of [***] no later than [***] after the date that the Parties mutually agree upon an Additional Target Program (including the Research Plan therefor) in accordance with Section 2.5, which fee will be payable one time per Additional Target Program (each, an "**Additional Target Program Payment**").

11.3 Research Milestones.

(a) On a Target Program-by-Target Program basis, Blueprint will pay to Proteovant each of the one-time milestone payments set forth in **Table 1** below (each, a "**Research Milestone Payment**") in accordance with Section 11.3(d) after the first achievement of the specified Research milestone event (each, a "**Research Milestone Event**"). Such payments will be non-creditable and non-refundable, and not subject to set-off.

Table 1

Research Milestone Event	Research Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) Each Research Milestone Payment will be paid only once for [***] for which the Research Milestone Payment is achieved, regardless of whether such milestone has already been achieved in connection with another [***].

(c) Each Research Milestone Payment will be deemed earned upon achievement of the corresponding Research Milestone Event in accordance with Section 2.3. Notwithstanding the foregoing, for the purposes of construing the payments specified in the above table, if an event in an applicable milestone is skipped (i.e., a later event payment is payable before an earlier event payment), then the skipped event(s) will be deemed to have been achieved upon the achievement of the subsequent event(s).

(d) Within [***] after such Research Milestone Event is achieved, Proteovant will invoice Blueprint the corresponding Research Milestone Payment, and Blueprint will pay such amount within [***] after the date of receipt of such invoice.

(e) If Proteovant exercises its Opt-In Right with respect to an Eligible Opt-In Program, then with respect to such Eligible Opt-In Program, the [***].

(f) Notwithstanding the foregoing, [***].

11.4 Development Milestones for Licensed Compounds and Licensed Products.

(a) On a Licensed Target Program-by-Licensed Target Program basis, Blueprint will pay to Proteovant each of the one-time development milestone payments set forth in **Table 2** below (each, a "**Development Milestone Payment**") in accordance with Section 11.4(d) after the first achievement of the specified development milestone event (each, a "**Development Milestone Event**") by the applicable Licensed Product. Such payments will be non-creditable and non-refundable, and not subject to set-off.

Table 2

	Development Milestone Event	Development Milestone Payment
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

[***]	[***]	[***]

(b) Each Development Milestone Payment will be paid only once for each [***] for which the Development Milestone Payment is achieved, regardless of whether such milestone has already been achieved in connection with another [***].

(c) Notwithstanding the foregoing, for the purposes of construing the payments specified in the above table, if [***]. Further, to the extent a Licensed Compound or corresponding Licensed Product achieves Regulatory Approval in a country or region in the Territory and an event is skipped [***].

(d) Blueprint will provide Proteovant with written notice of its achievement of each Development Milestone Event within [***] after such Development Milestone Event is achieved, and will make the corresponding Development Milestone Payment within [***] after receiving a corresponding invoice from Proteovant.

(e) If Proteovant exercises its Opt-In Right with respect to an Eligible Opt-In Program, then with respect to such Eligible Opt-In Program, [***].

11.5 Sales Milestone Payments.

(a) With respect to each Licensed Target Program, on a Licensed Target Program-by-Licensed Target Program basis, Blueprint will pay Proteovant each of the one-time sales milestone event payments set forth in the **Table 3** below (each, a "**Sales Milestone Payment**") in accordance with Section 11.5(c) after the first achievement of each of the corresponding sales milestone events (each, a "**Sales Milestone Event**") by the applicable Licensed Target Program, such payments will be non-refundable and non-creditable, and not subject to set-off.

Table 3

Sales Milestone Event	Sales Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) Each Sales Milestone Payment will be payable one time for each [***] for which the Sales Milestone Event is achieved, regardless of whether such milestone has already been achieved in connection with another [***].

(c) Blueprint will provide Proteovant with written notice of the achievement of each Sales Milestone Event within [***] such Sales Milestone Event is achieved, and will make the corresponding Sales Milestone Payment within [***] days after receiving a corresponding invoice from Proteovant. More than one Sales Milestones Payment in this Section 11.5 may be payable for a given [***] based on the Net Sales of the [***] in the same Calendar Year. For example, if more than one Sales Milestone Event specified in **Table 3** above is achieved in the same Calendar Year for a given [***], then each corresponding Sales Milestone Payment will be payable.

(d) In the event that Proteovant exercises its Opt-In Right, then with respect to the applicable Opt-In Target Program: [***].

11.6 Royalty Payments to Proteovant.

(a) **General**. Subject to the other provisions of this Article 11 and other provisions of this Agreement, in consideration of the licenses and ownership rights granted by Proteovant to Blueprint hereunder, with respect to each Licensed Target Program, on a Licensed Product-by-Licensed Product and country-by-country or region-by-region basis, as applicable, Blueprint will pay to Proteovant royalties based on the aggregate [***] Net Sales of such Licensed Product in the Territory during the applicable Royalty Term. Blueprint will pay to Proteovant on a [***] basis royalty payments with respect to each Licensed Product in a country or region for the duration of the Royalty Term for such Licensed Product in such country or region calculated by multiplying (i) Net Sales of such Licensed Product in such country or region in such [***] period by Blueprint, its Sublicensees and their Affiliates, by (ii) royalty rates as set forth in Table 4 below (subject to any offsets or reductions set forth below in this Section 11.6) tiered based upon the aggregated Net Sales of such Licensed Product in the Territory for such [***] up until the end of such [***].

Table 4

For that Portion of Total Aggregate [***] **Net Sales of a Licensed Product in the Territory**	**Royalty Rate**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For clarity, the Net Sales thresholds in the tables above will be determined on a Licensed Product-by-Licensed Product basis and the royalty rates above will only be applied such that a higher tiered royalty rate is only used after Net Sales in [***] exceeds the highest Net Sales threshold of the immediately previous lower tier, and such higher tiered royalty rate will only apply to the portion of Net Sales that falls within that tier. By way of example, if [***].

(b) Notwithstanding the foregoing, on a Licensed Product-by-Licensed Product and country-by-country or region-by region basis, as applicable, during any part of the Royalty Term for which the condition in clause (b) of the Royalty Term definition in Section 1.223 is met, with respect to such Licensed Product in such country or region, for the remaining part of the Royalty Term for so long as such condition continues to be met, [***].

(c) On a country-by-country basis, upon the First Commercial Sale in a country [***]"), the applicable royalty rate for [***] Net Sales, in such country for such Licensed Product will be [***] as follows: (i) [***].

(d) In the event that Proteovant exercises its Opt-In Right, then with respect to an Eligible Opt-In Program: [***].

(e) **Third Party Agreements**. If after the Effective Date, either Party reasonably determines that any Patents or other intellectual property owned or controlled by a Third Party is necessary or reasonably useful for the Research, Development, Manufacture, Commercialization or otherwise Exploitation of Collaboration Compounds, Licensed Compounds, Licensed Products, Blueprint Target Binder Compounds, [***], [***] or [***] in the Field in the Territory ("**Future In-Licensed IP**"), then such Party will promptly notify the other Party of such Future In-Licensed IP. Following such notification, [***].

(f) **Royalty Offset for Third Party Payments**. If Blueprint (or any of its Affiliates or Sublicensees) obtains a right or license under intellectual property of a Third Party that is [***] for the [***] of any Licensed Product by or on behalf of Blueprint (or any of its Affiliates or Sublicensees) in the Field in a particular country and that results in [***] to such Third Party, then [***], an amount equal to [***] paid by Blueprint (or any of its Affiliates or Sublicensees) to such Third Party for such right or license [***] during such [***].

(g) **Minimum Royalty**. In no event, after taking into account the reductions and deductions, alone or together, as set forth in this Section 11.6, will any royalties payable by Blueprint to Proteovant under this Section 11.6 for any Licensed Product in any country or region in any [***] be less than [***] of the amount of royalties that would otherwise be payable with respect thereto under Section 11.6(a) without taking into account such reductions and deductions; [***].

(h) **One Royalty**. For clarity, only one royalty will be due to Proteovant with respect to the same unit of Licensed Product.

(i) **Royalty Term**. Royalties payable by Blueprint to Proteovant under Section 11.6 will be paid on a Licensed Product-by-Licensed Product and country-by-country or region-by-region basis for the duration of the Royalty Term for such Licensed Product in such country or region. For clarity, (i) Blueprint will not owe royalties on any Licensed Product sold in a country or region after expiration of the Royalty Term for such Licensed Product in such country or region; and (ii) Net Sales of a Licensed Product sold in a country or region after expiration of the Royalty Term for such Licensed Product in such country or region will not be included as part of aggregated [***] Net Sales to determine whether a Sales Milestone Event has been achieved in Section 11.5(a) or to determine the applicable tiers of royalty rates under Section 11.6(a). Upon the expiration of

the Royalty Term with respect to a Licensed Product in a country or region, Blueprint will have a fully-paid-up perpetual license under Section 10.1(b) for the making, using, selling, offering for sale and importing of such Licensed Product in such country or region.

11.7 Royalty Payments and Reports.

(a) Within [***] during the Royalty Term for the applicable Licensed Product, Blueprint will provide Proteovant with a [***] report providing [***], on a Licensed Product-by-Licensed Product and country-by-country or region-by-region basis, of: (i) the amount of gross sales of Licensed Products in such country or region during the applicable [***] calculated in Dollars, and (ii) the amount of Net Sales of Licensed Products in such country or region during the applicable [***] calculated in Dollars, including an accounting of the deductions from gross sales to Net Sales.

(b) Within [***] during the Royalty Term for the applicable Licensed Product, Blueprint will provide Proteovant a royalty report providing a statement, on a Licensed Product-by-Licensed Product and country-by-country or region-by-region basis, of: (i) the amount of gross sales of Licensed Products in such country or region during the applicable [***] calculated in Dollars, (ii) the amount of Net Sales of Licensed Products in such country or region during the applicable [***] calculated in Dollars, including an accounting of the deductions from gross sales to Net Sales, (iii) a calculation of the amount of royalty payment due in Dollars on such Net Sales for such [***], (iv) the amount of withholding taxes, if any, required by Applicable Law to be deducted with respect to such royalties, calculated in Dollars, and (v) with respect to calculations applicable to countries outside of the U.S., the exchange rate used to calculate the foregoing amounts ((i)-(iv)). All amounts payable to Proteovant pursuant to Section 11.6 will be paid in accordance with Section 11.9 within [***] after the date of delivery of the corresponding royalty report is delivered to Proteovant.

11.8 Operating Profits or Losses in the Opt-In Territory and Development Cost Sharing in the Territory; Reconciliation Payments.

(a) **General**. The terms and conditions of this Section 11.8 will govern each Party's rights and obligations with respect to Shared Development Costs and Operating Profits or Losses in the Opt-In Territory, in each case relating to an Opt-In Product following Proteovant's exercise of its Opt-In Right with respect to an Opt-In Target Program.

(i) The Parties will share equally all Shared Development Costs with respect to each Opt-In Target Program in the Territory. Notwithstanding the foregoing, on a Calendar Year-by-Calendar Year basis, expenses charged by either Party as Shared Development Costs for an activity under an Opt-In Global Development Plan will not exceed [***].

(ii) The Parties will share equally the Operating Profits or Losses in the Opt-In Territory with respect to each Opt-In Target Program in accordance with the relevant then-current Operating Budget. [***].

(b) **Allocation of Costs to the Opt-In Product**. [***].

(c) **Calculation and Payment**.

(i) Following the exercise by Proteovant of its Opt-In Right with respect to an Opt-In Target Program, within [***] during the Opt-In Term for such Opt-In Target Program, (A) each Party will report to a finance officer designated by Blueprint and a finance officer designated by Proteovant (the "**Finance Officers**") a detailed, activity-based statement of its Shared Development Costs incurred in such [***], including, without limitation, [***] included in the Shared Development Costs (each a "**Development Cost Report**") and (B) each Party will provide the Finance Representatives with a detailed, activity-based statement of its Shared Commercialization Costs, including, without limitation, [***] included in the Shared Commercialization Costs (each a "**Commercial Cost Report**," and together with the Development Cost Reports, the "**Cost Reports**"), which will include a breakdown of the sub-categories of Shared Commercialization Costs, in each case to the extent incurred in such [***] (or [***] estimate of any portions thereof where actuals are not known as of such time) and directly allocable to the Development or Commercialization of such Opt-In Target Program, as well as details of any adjustments to be made to the amounts submitted in the previous [***] in previous Cost Reports. It is the intention of the Parties to interpret each of Shared Development Costs and Shared Commercialization Costs in accordance with Accounting Standards. [***] For reconciliation, billing and reporting hereunder, any costs included in the Costs Report incurred in a currency other than Dollars will be converted into Dollars in accordance with Section 11.11 below.

(ii) Concurrently with the Cost Reports, Blueprint will provide Proteovant and the JCC with a report setting forth Blueprint's [***] Net Sales and Fully-Burdened Manufacturing Costs for such Opt-In Product in the Opt-In Territory during such [***].

(iii) Within [***] after the end of each [***], each Party will provide to the Finance Officers a written, non-binding, preliminary report that will set forth, in a format to be mutually agreed by the Parties promptly following Proteovant's first exercise of an Opt-In Right with respect to an Opt-In Compound, such Party's [***] estimate of: (A) the amounts and information that will be set forward in such Party's Cost Reports for such [***]; and (B) in the case of Blueprint, the aggregate Net Sales and Fully-Burdened Manufacturing Costs of Opt-In Products in the Opt-In Territory. Within [***] after the end of each [***] and following receipt of Proteovant's Cost Report, Blueprint will provide to the Finance Officers with Operating Profits or Losses in the Opt-In Territory for such [***].

(iv) In addition to the preliminary reports to be provided by each Party in accordance with Section 11.8(c)(iii) above, within [***] after the end of each [***], the Finance Officers will provide the JSC a written report (the "**Reconciliation Report**") setting forth, in a format to be mutually agreed by the Parties promptly following Proteovant's first exercise of an Opt-In Right with respect to each Opt-In Target Program, the calculations of (A) the aggregate Shared Development Costs for such Calendar Quarter and each Party's share of such Shared Development Costs, (B) the aggregate Shared Commercialization Costs for such [***], if any, and each Party's share of such Shared Commercialization Costs, (C) the aggregate Net Sales of Opt-In Products in the Opt-In Territory, (D) Operating Profits or Losses in the Opt-In Territory for

such [***], if any, and (E) the net payment due from one Party to the other Party in accordance with the sharing percentages set forth in Section 11.8(a). Any net payment owed from one Party to the other Party will be paid within [***] following receipt of an invoice from such owed Party; provided that if a Party disputes an amount provided in such Reconciliation Report then such disputed amount will be reviewed by the JDC (with respect to Shared Development Costs) or JCC (with respect to Shared Commercialization Costs or Net Sales), as applicable, and any net payment owed with respect to the undisputed amounts will be paid within such [***] period (and the disputed amount, if determined to be owed, will be paid within [***] of resolution of the dispute); provided, further, that such dispute will not be subject to the final decision-making authority of the JSC, but will be resolved in accordance with Section 11.13 (by the audit report prepared by the independent public accounting firm commissioned to conduct the applicable audit by the disputing Party). If requested by Proteovant or Blueprint, any invoices or other supporting documentation for any payments to a Third Party related to cost sharing in the Opt-In Territory will be promptly provided, unless such invoices or other supporting documentation have been previously provided to an auditor designated by such requesting Party in accordance with Section 11.13.

(v) [***].

11.9 Payment Method. All payments due under this Agreement to a Party will be made by electronic funds transfer in immediately available funds to an account designated by such Party. All payments hereunder will be made in Dollars.

11.10 Taxes.

(a) **Taxes on Income, Tax Treatment**. Each Party will be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the collaborative efforts of the Parties under this Agreement. The Parties intend that the Co-Development of Licensed Products in the Opt-In Territory and Co-Commercialization of Licensed Products in the Opt-In Territory gives rise to a partnership solely for U.S. federal (and to the extent applicable, state and local) income tax purposes, and solely with respect to the Opt-In Territory, will be governed by terms substantially similar to the terms set forth in Schedule 11.10 with respect to the tax matters set forth therein.

(b) **Tax Cooperation**. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding, deductions or similar obligations in respect of royalties, milestone payments, and other payments made by Blueprint to Proteovant under this Agreement. Without limiting the foregoing, Proteovant will provide Blueprint with any required tax forms, if any, and other information that may be reasonably necessary in order for Blueprint to not withhold or deduct any taxes or similar obligations on payments made by Blueprint to Proteovant under this Agreement. Unless required under Applicable Law, Blueprint agrees not to withhold or deduct any taxes or similar obligations on any payment made to Proteovant under this Agreement. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

(c) **Payment of Tax**. To the extent Blueprint is required by Applicable Law to deduct or withhold taxes on any payment to Proteovant, Blueprint will notify Proteovant of such deduction or withholding, pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Proteovant a copy of a tax certificate or other evidence of such deduction or withholding sufficient to enable Proteovant to claim such payment of taxes or for a refund claim, as applicable.

(d) **Transfer Tax**. Subject to Section 11.10(a), Blueprint, on the one hand, and Proteovant, on the other hand, will each bear and pay fifty percent (50%) of any transfer, stamp, value added, sales, use, or similar taxes or obligations ("**Transfer Tax**") imposed on any transaction contemplated under this Agreement. Each Party will cooperate with the other to file any tax returns (as required to be filed under Applicable Law) with respect to such Transfer Taxes.

11.11 Foreign Exchange. All payments to be made by a Party under this Agreement will be made in Dollars, by wire transfer, pursuant to the instructions of the Party receiving payment, as designated from time to time. To the extent Shared Development Costs or Shared Commercialization Costs are incurred in a currency other than Dollars, the applicable expense will be converted into Dollars on a [***] basis using as a rate of exchange the average actual foreign currency exchange rate for the month in which the expense is incurred. Likewise, to the extent Licensed Products or Opt-In Products are sold in a currency other than Dollars, the amount received will be converted into Dollars on a monthly basis using as a rate of exchange the average actual foreign currency exchange rate for the month in which the expense is incurred. All currency conversions will be based on the OANDA foreign currency exchange rate (www.OANDA.com) or an equivalent resource as agreed by the Parties.

11.12 Records. Each Party will keep and will cause its Affiliates and licensees or sublicensees to keep, complete, true and accurate books of accounts and records sufficient to determine and establish the amounts payable incurred under this Agreement, and compliance with the other terms and conditions of this Agreement. Such books and records will be kept reasonably accessible and will be made available for inspection for a [***] period in accordance with Section 11.13 below.

11.13 Inspection of Records. Upon reasonable prior notice, each Party (the "**Auditing Party**") will permit an independent nationally recognized certified public accounting firm (subject to obligations of confidentiality to the other Party (the "**Audited Party**")), appointed by the Auditing Party and reasonably acceptable to the Audited Party, to inspect the audited financial records of the Audited Party during regular business hours to the extent relating to payments or cost sharing to the Auditing Party for a period of [***] from the creation of individual records for examination; provided, that such inspection will not occur more often than [***]. Any such auditor will 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 due by the Audited Party under this Agreement. Any inspection conducted under this Section 11.13 will be at the cost and expense of the Auditing Party, unless such inspection reveals any underpayment or overpayment by or to the Audited Party, as applicable, [***], in which case the full costs of such inspection for such period will be borne by the Audited Party. The Parties will reconcile any underpayment or overpayment within [***] after the accounting firm delivers the results of the audit, provided that (a) if as a result, Blueprint will

pay any amount to Proteovant, Blueprint will pay such amount within [***] after receiving a corresponding invoice from Proteovant (and for any portion in such amount that was underpaid by Blueprint (but not overpaid by Proteovant), with interest at the rate specified in Section 11.14 from the date such underpaid amount was originally due), and (b) if as a result, Proteovant will pay any amount to Blueprint, Blueprint will credit such amount against future amounts due by Blueprint to Proteovant, or, if no future amounts are due at that time, Proteovant will pay such amount to Blueprint within [***] after receiving a corresponding invoice from Blueprint.

11.14 Late Payments. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a per annum rate equal to the lesser of: (a) [***] percentage points above the prime rate as reported in The Wall Street Journal, Eastern Edition on the first day of each [***] in which such payments are overdue or (b) the maximum rate permitted by Applicable Law.

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

12. OWNERSHIP OF INVENTIONS, PATENT PROSECUTION AND ENFORCEMENT

12.1 Ownership of Information and Inventions.

(a) **General**. Except as expressly set forth in Section 12.1(c), as between the Parties, each Party will own all Information (and Patents that claim such Information (collectively, "**Sole Patents**")) solely conceived, discovered, developed or otherwise made by or on behalf of it or its Affiliates or their respective employees, agents or independent contractors in the course of conducting such Party's activities under this Agreement (collectively, "**Sole Know-How**"). All Information (and Patents that claim such Information (collectively, "**Joint Patents**")) conceived, discovered, developed or otherwise made jointly by Blueprint or its Affiliates or their respective employees, agents, or independent contractors and Proteovant or its Affiliates or their respective employees, agents, or independent contractors in the course of conducting activities under this Agreement (collectively, "**Joint Know-How**") will be owned jointly by the Parties. Subject to the rights and licenses granted under this Agreement, including the payment of royalties under Section 11.6, it is understood that neither Party will have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign or otherwise exploit such Joint Know-How and Joint Patents, by reason of joint ownership thereof, and each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting; provided, however, that on a Target Program-by-Target Program basis prior to the earlier of (A) the applicable Option Exercise Date and (B) the last day of the applicable Option Exercise Period, neither Party will exercise any rights, or grant any Third Party any rights, under the Joint Know-How and Joint Patents, other than to conduct its activities (including through the use of Third Party contractors) under the applicable Research Plan. Each Party will take all actions and provide the other Party with all reasonably requested assistance to effect the assignments described in this Section 12.1(a) and will execute any and all documents necessary to perfect such assignments.

(b) **Disclosure of Inventions**. Each Party will promptly disclose to the other Party all inventions, including receipt of any invention disclosures submitted to such Party by its or its Affiliates' respective employees, agents or independent contractors (including CROs) describing inventions conceived, discovered, developed or otherwise made by or behalf of such Party or its Affiliates in the course of conducting activities under this Agreement. Each Party will also respond promptly to reasonable requests from the other Party for more Information relating to such inventions.

(c) **Exceptions**.

(i) As between the Parties, on a Licensed Target Program-by-Licensed Target Program basis, following the applicable Option Exercise Date (the "**IP Assignment Date**"), with respect to the Licensed Compounds and Licensed Products under such Licensed Target Program, subject to Section 12.1(c)(iii), Blueprint will solely own any Collaboration Patents that [***] claim [***] (each such Patent, a "**Product Patent**"). Effective upon the IP Assignment Date, Proteovant will take all actions and provide Blueprint with all reasonably requested assistance to effect such assignment and will execute any and all documents necessary to perfect such assignment.

(ii) As between the Parties, Blueprint will solely own: (A) any Collaboration Know-How that [***] relates to any Blueprint Target Binder Compounds (the "**Blueprint Target Binder Compound Know-How**"); and (B) any Collaboration Patents that Cover such Collaboration Know-How or such Blueprint Target Binder Compounds (the "**Blueprint Target Binder Compound Patents**") or any method of making or using such Blueprint Target Binder Compounds. Proteovant and its Affiliates will, and hereby do, assign to Blueprint or one or more of its designated Affiliates, its and its Affiliates' rights, title and interest in any Blueprint Target Binder Compound Know-How or Blueprint Target Binder Compound Patents. Proteovant will take all actions and provide Blueprint with all reasonably requested assistance to effect such assignment and will execute any and all documents necessary to perfect such assignment.

(iii) As between the Parties, Proteovant will solely own: (A) any Collaboration Know-How that [***] relates to any Proteovant [***] or Proteovant [***] or combination thereof (the "**Proteovant** [***] **Know-How**"), and (B) any Collaboration Patents that Cover such Collaboration Know-How or such Proteovant [***] or Proteovant [***] or combination thereof (the "**Proteovant** [***] **Patents**") [***]. Blueprint and its Affiliates will, and hereby do, assign to Proteovant or one or more of its designated Affiliates, its and its Affiliates' rights, title and interest in any Proteovant [***] Know-How and Proteovant [***] Patents. Blueprint will take all actions and provide Proteovant with all reasonably requested assistance to effect such assignment and will execute any and all documents necessary to perfect such assignment.

(d) **Inventorship**. Inventorship for patentable inventions conceived of during the course of the performance of activities pursuant to this Agreement will be determined in accordance with U.S. Patent laws for determining inventorship and other Applicable Law in the U.S. without regard to conflict of law, irrespective of where or when such conception, discovery, development or making occurs. If U.S. law otherwise would not apply to the conception, reduction

to practice, discovery, development or other making of any Information or inventions hereunder, each Party will, and does hereby, assign, and will cause its Affiliates and its and their licensees or sublicensees (including Sublicensees with respect to Blueprint) to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Information and inventions as well as any Intellectual Property Rights with respect thereto, as is necessary to fully effect, as applicable, the sole ownership or the joint ownership provided for in Section 12.1(a) or 12.1(b) or 12.1(c). Each Party will have the right to request for inventorship interviews to be conducted by a Third Party.

12.2 Prosecution of Patents.

(a) **Before Option Exercise**.

(i) On a Target Program-by-Target Program basis, prior to the earlier of (A) the applicable Option Exercise Date and (B) the last day of the applicable Option Exercise Period, Proteovant will have the first right, but not the obligation, at its sole expense, to draft, file, prosecute and maintain (including the defense of any oppositions, appeals, interferences, reissue proceedings, reexaminations and post-grant and administrative proceedings) in all jurisdictions in the Territory (collectively, "**Prosecute**") the Proteovant Patents and the Joint Patents using outside counsel of its choice and reasonably acceptable to Blueprint. Proteovant or Proteovant's outside counsel will keep Blueprint reasonably informed of its progress with respect to the Proteovant Patents and the Joint Patents and Proteovant will provide Blueprint with copies of any material documents it receives or prepares in connection with the Prosecution of such Patents filed in the applicable Territory and will inform Blueprint of the progress of such documents. Before filing any document with a patent office in connection with the Prosecution of the Proteovant Patents or Joint Patents, Proteovant or Proteovant's outside counsel will provide a copy of such document to Blueprint sufficiently in advance to enable Blueprint to comment on it, and Proteovant will give due consideration to such comments and will reasonably incorporate any of such comments in Proteovant's filings or responses to the extent such comments are provided sufficiently in advance of any applicable filing deadlines. In the event that Proteovant elects not to Prosecute in any country any Patent within the Proteovant Patents or Joint Patents, Proteovant will give Blueprint at least [***] notice before any relevant deadline and provide to Blueprint information it reasonably requests relating to such Patent. Blueprint will then have the right to assume responsibility, using outside counsel of its choice, for the Prosecution of such Patent. If Blueprint assumes responsibility for the Proteovant Patents or Joint Patents as set forth above, then the Patent Prosecution Costs incurred by Blueprint and its counsel in the course of such Prosecution will thereafter be borne by Blueprint.

(ii) The Parties will cooperate [***] to ensure that, on a Target Program-by-Target Program basis, prior to the earlier of exercise of the Option by Blueprint with respect to such Target Program in accordance with Section 3.3 and expiration of the Option Exercise Period for such Target Program, patent applications Covering the Collaboration Compounds are made at a time and with a scope that will maximize the commercial potential of any related Licensed Compounds and Licensed Products. For clarity, the Parties may agree not to file any patent applications prior to Option Exercise by Blueprint.

(b) **After Option Exercise**.

(i) On a Licensed Target Program-by-Licensed Target Program basis following Blueprint's exercise of the Option with respect to such Licensed Target Program in accordance with Section 3.3, Blueprint will have the first right, but not the obligation, at its sole expense, to Prosecute the Product Patents, Proteovant Patents, and Joint Patents using outside counsel of its choice and reasonably acceptable to Proteovant; provided, however, that at Blueprint's request, Proteovant will prepare the initial draft applications or certain sections of the initial draft applications for such Product Patents, Proteovant Patents, and Joint Patents.

(ii) In the event Proteovant exercises its Opt-In Right with respect to an Eligible Opt-In Program, then, with respect to the applicable Opt-In Compound and Opt-In Product, Blueprint or Blueprint's outside counsel will keep Proteovant reasonably informed of its progress, with respect to such Product Patents, Proteovant Patents, and Joint Patents for Opt-In Compounds and Opt-In Products in the Opt-In Territory, and Blueprint or Blueprint's outside counsel will provide Proteovant with copies of any material documents it receives or prepares in connection with the Prosecution of such Product Patents, Proteovant Patents, or Joint Patents filed in the Opt-In Territory and will inform Proteovant of the progress of such documents. Before filing any document with a patent office in connection with the Prosecution of such Product Patents, Proteovant Patents, or Joint Patents, Blueprint or Blueprint's outside counsel will provide a copy of such document to Proteovant sufficiently in advance to enable Proteovant to comment on it, and Blueprint will give due consideration to such comments and will reasonably incorporate any of such comments in Blueprint's filings or responses to the extent such comments are provided sufficiently in advance of any applicable filing deadlines. The Parties will cooperate [***] to ensure that patent applications Covering the Licensed Compounds and Licensed Products are made at a time and with a scope that will maximize the commercial potential of the Licensed Compounds and Licensed Products.

(iii) In the event that Blueprint elects not to Prosecute in any country any Patent within such Product Patents, Proteovant Patents, or Joint Patents, Blueprint will give Proteovant at least [***] notice before any relevant deadline and provide to Proteovant information it reasonably requests relating to such Product Patent, Proteovant Patents, or Joint Patent. Proteovant will then have the right to assume responsibility, using outside counsel of its choice, for the Prosecution of such Product Patent, Proteovant Patents, or Joint Patent. If Proteovant assumes responsibility for such Product Patents, Proteovant Patents, or Joint Patents as set forth above, then the Patent Prosecution Costs incurred by Proteovant and its counsel in the course of such Prosecution will thereafter be borne by Proteovant.

12.3 Patent Term Extensions. Blueprint will have the sole right, but not the obligation, to apply for any such extensions (or supplemental protection certificates or their equivalents in any country) with respect to the Licensed Product and for the Product Patents, Proteovant Patents, and Joint Patents. Proteovant will cooperate fully with and provide all reasonable assistance to Blueprint and use all Commercially Reasonable Efforts consistent with its obligations under Applicable Law (including any applicable consent order or decree) in connection with obtaining any such extensions for the Product Patents, Proteovant Patents, and Joint Patents.

12.4 Orange Book and Other Equivalent Listing. Blueprint will have the sole right to make any patent listing filings in the FDA Orange Book (and any foreign equivalents in any

country) with respect to the Licensed Product and any Product Patents, Proteovant Patents, or Joint Patents.

12.5 CREATE Act. This Agreement will be understood to be a joint research agreement under 35 U.S.C. §103(c)(3) entered into for the purpose of researching, identifying and developing Collaboration Compounds, Licensed Compounds or Licensed Products under the terms set forth herein, provided that that neither Party will (a) unilaterally invoke the protections of or (b) be required by this reference to have any Patent take advantage of or become subject to, such §103(c) except with the prior written consent of the other Party.

12.6 Prosecution and Enforcement of Other Patents.

(a) **Blueprint Patents**. Blueprint will have the sole right and authority (but not the obligation), at its sole cost, to Prosecute, defend and enforce the Blueprint Target Binder Compound Patents in any jurisdiction and will inform Proteovant of the progress of such documents.

(b) **Proteovant Patents**.

(i) As between the Parties, Proteovant will have the first right (but not the obligation), at its sole cost to Prosecute, defend and enforce the Proteovant [***] Patents. For any Proteovant [***] Patents that Cover a Licensed Compound or Licensed Product, Proteovant will provide Blueprint with copies of any material documents it receives or prepares in connection with the Prosecution of such Proteovant [***] Patents and will inform Blueprint of the progress of such documents. Before filing in connection with such Prosecution any document with a patent office, Proteovant or Proteovant's outside counsel will provide a copy of such document to Blueprint sufficiently in advance to enable Blueprint to comment on it, and Proteovant will give due consideration to such comments and will reasonably incorporate any of such comments in Proteovant's filings or responses to the extent such comments are provided sufficiently in advance of any applicable filing deadlines. Prior to the filing of any Patent for a Proteovant [***] Patent that Covers Licensed Compounds or Licensed Products, the Patent Contacts will meet to discuss the filing strategy for such Patent, including identifying and dividing, if applicable, subject matter pertaining to Proteovant [***] or Proteovant [***] or combinations thereof that are [***] related to Licensed Compounds or Licensed Products directed to the Collaboration Target from subject matter that is not [***] related to Licensed Compounds or Licensed Products directed to the Collaboration Target. For clarity, such subject matter that is not [***] related to Licensed Compounds or Licensed Products directed to the Collaboration Target is subject matter [***] (other than the Licensed Compounds) [***].

(ii) In the event that Proteovant elects not to Prosecute in any country any Patent within such Proteovant [***] Patents that Cover a Licensed Compound or Licensed Product, Proteovant will give Blueprint at least [***] notice before any relevant deadline and provide to Blueprint information it reasonably requests relating to such Proteovant [***] Patents. Blueprint will then have the right to assume responsibility, using outside counsel of its choice, for the Prosecution of such Proteovant [***] Patents. If Blueprint assumes responsibility for the Proteovant [***] Patents as set forth above, then the Patent Prosecution Costs incurred by Blueprint and its counsel in the course of such Prosecution will thereafter be borne by Blueprint.

12.7 Cooperation.

(a) Each Party will provide the other Party all reasonable assistance and cooperation for such Party to exercise its rights and perform its obligations pursuant to this Article 12, including with respect to the Prosecution of the Product Patents, Proteovant Patents, Joint Patents, Blueprint Target Binder Compound Patents, and Proteovant [***]Patents that Cover a Licensed Compound or Licensed Product. Without limiting the generality of the foregoing, each Party will provide the other Party with all any and all necessary powers of attorney and will execute any other required documents or instruments necessary to Prosecute such Patents, and each Party agrees to provide the other Party with all information necessary or reasonably desirable to enable the other Party to comply with the duty of disclosure requirements of any patent authority.

(b) Prior to the filing of any Product Patents, Proteovant Patents, Joint Patents, Blueprint Target Binder Compound Patents, and Proteovant [***] Patents that Cover a Licensed Compound or Licensed Product, the Patent Contacts will meet and [***] discuss and agree on the Prosecution strategy for such Patents.

12.8 Competitive Infringement by Third Parties.

(a) **Notification**. The Parties will promptly notify each other of any actual, threatened, alleged or suspected infringement by a Third Party of the Proteovant Patents, Product Patents, or Joint Patents (a "**Competitive Infringement**"). A notice under 21 U.S.C. 355(b)(3) or 355(j)(2)(B) or under 42 U.S.C. 262(l) (as such section may be amended from time to time during the Term) with respect to a Licensed Compound or Licensed Product will be deemed to describe an act of Competitive Infringement, regardless of its content. As permitted by Applicable Law, each Party will promptly notify the other Party in writing of any such Competitive Infringement of which it becomes aware and will provide evidence in such Party's possession demonstrating such Competitive Infringement. In particular, each Party will notify and provide the other Party with copies of any allegations of patent invalidity, unenforceability or non-infringement of any Proteovant Patents, Product Patents or Joint Patents Covering a Licensed Compound or Licensed Product (including methods of use or manufacture thereof). Such notification and copies will be provided by the Party receiving such certification to the other Party as soon as practicable and, unless prohibited by Applicable Law, at least within [***] days after the receiving Party receives such certification.

(b) **Enforcement of Product Patents, Proteovant Patents and Joint Patents**. Blueprint will have the first right, but not the obligation, to bring and control, at its cost and expense, an appropriate suit or other action before any government or private tribunal against any person or entity allegedly engaged in any Competitive Infringement of any Product Patent, Proteovant Patent, or Joint Patent ("**Product Specific Infringement Action**") to remedy the Competitive Infringement (or to settle or otherwise secure the abatement of such Competitive Infringement). The foregoing right of Blueprint will include the right to perform all actions of a reference product sponsor set forth in 21 U.S.C. 355(b)(3) or 355(j)(2)(B) or under 42 USC 262(l). Proteovant will have the right, at its own cost and expense and by counsel of its choice, to be represented in (but not control) any Product Specific Infringement Action. At Blueprint's request, Proteovant will join any Product Specific Infringement Action as a party (at Blueprint's cost and expense) if doing so is necessary for the purposes of establishing standing or is otherwise required

by Applicable Law to pursue such action. Blueprint will have a period of [***] after its receipt or delivery of notice and evidence pursuant to Section 12.8(a) to elect to so enforce such Product Patents, Proteovant Patents, or Joint Patents in the applicable jurisdiction to remedy the Competitive Infringement (or to settle or otherwise secure the abatement of such Competitive Infringement), provided, however, that such period will be more than [***] to the extent Applicable Law prevents earlier enforcement of such Product Patents, Proteovant Patents or Joint Patents (such as the enforcement process set forth in 21 U.S.C. 355(b)(3) or 355(j)(2)(B) or under 42 USC 262(l)). In the event Blueprint does not so elect to remedy the Competitive Infringement (or settle or otherwise secure the abatement of such Competitive Infringement) within the aforementioned period of time for the filing of a Product Specific Infringement Action, it will so notify Proteovant in writing and in the case where Proteovant then desires to commence a suit or take action to enforce the applicable Product Patents, Proteovant Patents, or Joint Patents with respect to such Competitive Infringement (or settle or otherwise secure the abatement of such Competitive Infringement) in the applicable jurisdiction, Proteovant will have the right to commence such a suit or take such action to enforce the applicable Product Patents, Proteovant Patents, or Joint Patents with respect to such Competitive Infringement (or settle or otherwise secure the abatement of such Competitive Infringement), at Proteovant's cost and expense. Each Party will provide to the Party enforcing any such rights under this Section 12.8(b) reasonable assistance in such enforcement, at such enforcing Party's request and cost and expense, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. The enforcing Party will keep the other Party regularly informed of the status and progress of such enforcement efforts and will reasonably consider the other Party's comments on any such efforts.

(c) **Settlement**. Without the prior written consent of the other Party (not to be unreasonably withheld, conditioned or delayed), neither Party will settle any Product Specific Infringement Action in any manner that would adversely affect such Product Patents, Proteovant Patents, or Joint Patents (provided that Blueprint will have the right to grant (sub)licenses under such Product Patents, Proteovant Patents or Joint Patents in its sole discretion and Proteovant will reasonably cooperate with such efforts) or that would limit or restrict the ability of Blueprint (or its Affiliates or its or their Sublicensees, as applicable) to sell Licensed Products anywhere in the Territory.

(d) **Expenses and Recoveries**. A Party bringing a Product Specific Infringement Action under this Section 12.8 against any Third Party engaged in Competitive Infringement of such Product Patents, Proteovant Patents, or Joint Patents will be solely responsible for any costs and expenses incurred by such Party as a result of such Product Specific Infringement Action. If such Party recovers monetary damages from such Third Party in such Product Specific Infringement Action, such recovery will first be applied to all Out-of-Pocket costs and expenses incurred by the Parties in connection therewith, including attorneys' fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it will be shared pro-rata in proportion to the relative amount of such costs and expenses incurred by each Party. If after such reimbursement any funds remain from such damages, such funds will be shared as follows: [***] of such amount of any recovery remaining will be retained by or paid to the Party initiating such action, and [***] of such amount of any recovery remaining will be retained by or paid to the other Party; provided, however, that to the extent any such amount is awarded as imputed net sales of Licensed Products or a reasonable royalty on net sales of Licensed Products, then such amount will be exclusively paid to Blueprint and treated as Net Sales with respect to the applicable periods

and territories for which such recovery was calculated, for purposes of calculating royalties payable to Proteovant pursuant to Section 11.6 or Proteovant's share of Operating Profits or Losses in the Opt-In Territory pursuant to Section 11.8.

12.9 Third Party Rights.

(a) The Parties will promptly notify each other of becoming aware of any allegation that any activity pursuant to this Agreement infringes or misappropriates the Patents of any Third Party. In addition, the Parties will notify each other if either Party desires to obtain a license or otherwise pursue a defense or settlement with respect to any allegation of infringement or misappropriation of such Third Party Patent that may be considered to Cover Licensed Compounds or Licensed Products or their Manufacture or use in accordance with Section 11.6(e).

(b) Subject to Section 12.9(c), 12.9(d) and 12.9(e), with respect to any Third Party Patent under Section 12.9(a), and without limiting the right of a Party against whom a claim of infringement of any Third Party Patent is filed to seek indemnification for such claim pursuant to Article 18, as between the Parties, notwithstanding any right of the Indemnifying Party to control as set forth in Section 18.3, [***].

(c) Notwithstanding the foregoing, in the case a claim of infringement of a Patent is brought against a Party in a suit or other action or proceeding with respect to any Third Party Patent under Section 12.9(a), such Party will have the right, at its own cost and expense and by counsel of its own choice, to prosecute and defend any such claim in such suit or other action or proceeding. If both Parties are named, the Parties will meet and determine who is best situated to lead any such suit or other action or proceeding.

(d) Without the prior written consent of the other Party (not to be unreasonably withheld, conditioned or delayed), neither Party will settle any claim under this Section 12.9 in any manner that would impose any material obligations, restriction or limitation on the other Party.

(e) The Parties will reasonably cooperate with one another in prosecuting or defending any action pursuant to this Section 12.9.

12.10 Patent Challenges.

(a) The Parties will promptly notify each other in the event that any Third Party files, or threatens to file, any paper in a court or other Governmental Authority, seeking to invalidate, reexamine, oppose or compel the licensing of the Proteovant Patents, Product Patents or Joint Patents (any such Third Party action being a "**Patent Challenge**").

(b) As between the Parties, Blueprint will have the first right, but not the obligation, to bring and control, at its cost and expense (but without limiting its right to seek indemnification, if applicable), any effort in defense of such a Patent Challenge against a Product Patent, Proteovant Patent, or Joint Patent, except in the case where such Patent Challenge is made in connection with a Product Specific Infringement Action, in which case the enforcing Party in the Product Specific Infringement Action will have the first right, but not the obligation, to bring and control the defense of such Patent Challenge and such Patent Challenge will be considered part of the Product Specific Infringement Action under this Article 12. In the case where Blueprint

controls the defense of such Patent Challenge, Proteovant will have the right, at its own cost and expense and by counsel of its choice, to be represented in (but not control) any such effort. If Blueprint fails to take action to defend such Patent Challenge within [***] of the time limit for bringing such defense (or within such shorter period to the extent that a delay in bringing such defense would limit or compromise the outcome of such defense of such Patent Challenge), then Proteovant will have the right, but not the obligation, to bring and control any effort in defense of such Patent Challenge at its own cost and expense (but without limiting its right to seek indemnification, if applicable). Notwithstanding the foregoing, if Blueprint has any [***] grounds for believing that Proteovant's exercise of its backup defense right with respect to any such Product Patent, Proteovant Patent, or Joint Patent could reasonably be detrimental to the overall Patent protection of the Collaboration Compounds, Licensed Compounds or Licensed Products as discussed by the Patent Contacts, then Proteovant will not be permitted to defend such Product Patent, Proteovant Patent, or Joint Patent without the prior written consent of Blueprint, in Blueprint's discretion.

(c) Proteovant will have the sole right, but not the obligation, to bring and control, at its own cost and expense, any effort in defense of such a Patent Challenge related to any Proteovant [***] Patent. In the case where Proteovant controls the defense of such Patent Challenge related to any [***] Patent that Covers a Licensed Compound or Licensed Product, Blueprint will have the right, at its own cost and expense and by counsel of its choice, to be represented in (but not control) any such effort. If Proteovant fails to take action to defend such Patent Challenge with respect to a Proteovant [***] Patent included within the Exclusively Licensed Proteovant [***] Technology within [***] of the time limit for bringing such defense (or within such shorter period to the extent that a delay in bringing such defense would limit or compromise the outcome of such defense of such Patent Challenge), then Blueprint will have the right, but not the obligation, to bring and control any effort in defense of such Patent Challenge at its own cost and expense (but without limiting its right to seek indemnification, if applicable). Notwithstanding the foregoing, if Proteovant has any [***] grounds for believing that Blueprint's exercise of its backup defense right with respect to any such Proteovant [***] Patent could reasonably be detrimental to the overall Patent protection of the Proteovant [***] or Proteovant [***] as discussed by the Patent Contacts, then Blueprint will not be permitted to defend such Proteovant [***] Patent without the prior written consent of Proteovant, in Proteovant's discretion.

(d) Blueprint will have the sole right, but not the obligation, to bring and control, at its own cost and expense, any effort in defense of such a Patent Challenge related to any Blueprint Target Binder Compound Patent.

12.11 Patent Contacts. Each Party will designate patent counsel representatives with the appropriate expertise in the subject matter who will be responsible for coordinating the activities between the Parties in accordance with this Article 12 (each a "**Patent Contact**"). Each Party will designate its initial Patent Contact within [***] following the Effective Date and will promptly thereafter notify the other Party of such designation. If at any time a vacancy occurs for any reason, the Party that appointed the prior incumbent will as soon as reasonably practicable appoint a successor. Each Party will promptly notify the other Party of any substitution of another person as its Patent Contact. The Patent Contacts will, from time to time, facilitate information sharing, coordinate the respective patent strategies of the Parties relating to this Agreement, and address any other matters for which the Parties are obligated to cooperate, keep each other informed or

otherwise communicate under this Article 12. The Patent Contacts will have solely the roles and responsibilities assigned to them in this Section 12.11, and the Patent Contacts will have no authority to amend, modify or waive compliance with this Agreement.

12.12 Personnel Obligations.

(a) Prior to receiving any Confidential Information or beginning work under the Target Program, each employee, agent or independent contractor (including, with respect to Proteovant, [***]) of Blueprint or Proteovant or of either Party's respective Affiliates will be bound in writing by non-disclosure and invention assignment obligations that are consistent with the obligations of Blueprint or Proteovant under this Agreement (provided that where necessary in the case of a Third Party (i) with respect to any activities to be conducted by such Third Party under a Research Plan, such Third Party will agree to grant Blueprint or Proteovant, as the case may be, ownership or an exclusive license with the right to grant sublicenses with respect to resulting inventions and Patents; provided that such obligation to obtain ownership or an exclusive license will not apply to any improvements to the proprietary core or platform technology owned or in-licensed by such Third Party, and instead, such Third Party will agree to grant Blueprint or Proteovant, as the case may be, a non-exclusive license with the right to grant sublicenses with respect to such improvements; and (ii) the period of time with respect to non-disclosure obligations may be shorter, if customary).

(b) Without limiting the generality of the foregoing, each Party and its Affiliates will, and will cause its sublicensees to, enter into an agreement or employment policy with each of its employees performing activities under this Agreement that (i) compels prompt disclosure to such Party (or its Affiliates or sublicensee, as applicable) of all Collaboration Technology developed, invented, or filed by such employee during any performance under this Agreement; and (ii) automatically assigns to such Party (or its Affiliates or sublicensee, as applicable) all rights, title, and interests in and to all Collaboration Technology, and requires each employee to execute all documents and take such other actions as may be necessary to effectuate such assignment. Each Party will enter into such written agreement or employment policy no later than [***] after the Effective Date to the extent necessary to comply with its obligations under this Section 12.12(b).

(c) Each Party (or its Affiliates or sublicensees, as applicable) will be responsible for any reward or remuneration required under Applicable Law to be paid to such Party's (or its Affiliates' or sublicensees', as applicable) employees with respect to any activities to be conducted under a Research Plan.

13. TRADEMARKS

13.1 Licensed Product Trademarks. Blueprint will be solely responsible for the selection (including the creation, searching and clearing), registration, maintenance, policing and enforcement of all trademarks developed for use in connection with the marketing, sale or distribution of Licensed Compounds and Licensed Products in the Field in the Territory (the "**Product Marks**"). As between the Parties, Blueprint will own all Product Marks, and all trademark registrations for said marks. Following Proteovant's exercise of the Opt-In Right, Blueprint will grant Proteovant a right to use such Product Marks in the Opt-In Territory.

13.2 Use of Name. Neither Party will, without the other Party's prior written consent, use any trademarks or other marks of the other Party (including the other Party's corporate name), advertising taglines or slogans confusingly similar thereto, in connection with such Party's marketing or promotion of Licensed Compounds or Licensed Products under this Agreement in the Territory or for any other purpose, except as may be expressly authorized in writing in connection with activities under this Agreement and except to the extent required to comply with Applicable Law.

13.3 Further Actions. Each Party will, upon the reasonable request of the other Party, provide such assistance and execute such documents as are reasonably necessary for such Party to exercise its rights or perform its obligations pursuant to this Article 13; provided, however, that neither Party will be required to take any action pursuant to this Article 13 that such Party reasonably determines in its sole judgment and discretion conflicts with or violates any applicable court or government order or decree or Applicable Law.

14. EXCLUSIVITY

14.1 Exclusivity Regarding Research, Development and Commercialization of Collaboration Compounds.

(a) Subject to this Article 14, on a Target Program-by-Target Program basis, during the Option Exercise Period for such Target Program, and, if Blueprint exercises its Option with respect to such Target Program, commencing on the Option Exercise Date for such Target Program and continuing during the Term, except pursuant to a Research Plan, neither Party will, for itself, or with, through or for its Affiliates or any Third Party (including the grant of any license, option or other right to any Third Party), directly or indirectly, research, develop, manufacture, commercialize or otherwise Exploit any Competing Product with respect to such Target Program anywhere in the Territory.

(b) Notwithstanding the foregoing, prior to achievement of the [***] set forth in the relevant Research Plan for a given Target Program, Blueprint will have the right to use, research, develop and manufacture the applicable Blueprint Target Binder Compounds and derivatives of such Blueprint Target Binder Compounds for [***].

14.2 Exceptions.

(a) The restrictions set forth in Section 14.1 will not apply to a Party's or its or any of its Affiliates' exercise of rights and performance of obligations under and in accordance with this Agreement, including under the Co-Commercialization Agreement, if any.

(b) The Parties hereby acknowledge and agree that the restrictions set forth in Section 14.1 will not apply to any activities intended by each Party or any of its Affiliates to ensure its compliance with Section 14.1 (*e.g.*, counter-screening).

14.3 Acquisition of Distracting Product. Notwithstanding the provisions of Section 14.1, if a Party or any of its Affiliates acquires rights to research, develop or commercialize a product in the Field as the result of a merger, acquisition or combination with or of a Third Party other than a Change of Control of such Party (each, an "**Acquisition Transaction**") and, on the

date of the closing of such Acquisition Transaction, such product is being researched, developed or commercialized and such activities would, but for the provisions of this Section 14.3, constitute a breach of Section 14.1 (such product, a "**Distracting Product**"), such Party will, within [***]:

[***].

14.4 Change of Control. If there is a Change of Control of a Party, the obligations of Section 14.1 will not apply to any program, compound or product of the Acquirer; provided that [***].

15. CONFIDENTIALITY

15.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party (the "**Receiving Party**") agrees that, for the Term and for [***] thereafter, it will keep confidential and will not publish or otherwise disclose and will not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information of the other Party (the "**Disclosing Party**") pursuant to this Agreement except for that portion of such Confidential Information that the Receiving Party can demonstrate by competent written proof:

(a) was already known to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality or any restriction on its use to the Disclosing Party, at the time of disclosure by the other Party; provided, however, this exception will not apply with respect to Licensed Compound Information, or Confidential Information that is deemed to be the Confidential Information of both Parties under this Agreement;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without obligations of confidentiality or restrictions on its use to the Disclosing Party with respect thereto; provided, however, this exception will not apply with respect to Confidential Information that is deemed to be the Confidential Information of both Parties under this Agreement; or

(e) is subsequently independently discovered or developed by or on behalf of the Receiving Party or its Affiliates without the aid, application, or use of Confidential Information of the Disclosing Party, as demonstrated by documented evidence prepared contemporaneously with such independent development; provided, however, this exception will not apply with respect to Licensed Compound Information, or Confidential Information that is deemed to be the Confidential Information of both Parties under this Agreement.

Any combination of features or disclosures will not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party, and any individual feature or disclosure will not be deemed to fall within the foregoing exclusions merely because a broader or related combination of such feature or disclosure is published or available to the general public unless the individual feature or disclosure itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

15.2 Authorized Disclosure. Notwithstanding the obligations of confidentiality and non-use set forth in Section 15.1, each Party may disclose Confidential Information of the Disclosing Party to the extent such disclosure is reasonably necessary in the following situations:

(a) filing or prosecuting Patents in accordance with Article 12;

(b) subject to Section 15.3, regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), including filings with the FDA or other Regulatory Authorities, as necessary for the Development or Commercialization of a Collaboration Compound or the corresponding Licensed Compound and Licensed Product(s), as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures will be taken to seek confidential treatment of such information, if available;

(c) prosecuting or defending litigation;

(d) with respect to either Party, disclosure to its Affiliates and its and their employees to the extent such Affiliates and employees are conducting activities under this Agreement with respect to a Target Program, Licensed Target Program or Opt-In Target Program; provided, that each disclosee must be bound by obligations of confidentiality and non-use at least as equivalent in scope as and no less restrictive than those set forth in this Article 15 prior to any such disclosure (but of shorter duration, if customary);

(e) subject to Section 15.3, complying with Applicable Law, including regulations promulgated by securities exchanges;

(f) disclosure of this Agreement (including its material terms) to any bona fide [***] on a reasonable need-to-know basis; provided, that each disclosee must be bound by obligations of confidentiality and non-use at least as equivalent in scope as and no less restrictive than those set forth in this Article 15 prior to any such disclosure (but of shorter duration, if customary);

(g) disclosure of the stage of research or Development of Collaboration Compounds or the corresponding Licensed Compounds of Licensed Products under this Agreement (but no other Licensed Compound Information) to any bona fide [***]; provided, that each disclosee must be bound by obligations of confidentiality and non-use at least as equivalent

in scope as and no less restrictive than those set forth in this Article 15 prior to any such disclosure (but of shorter duration, if customary);

(h) solely to potential or actual research and development collaborators, subcontractors, sublicensees, advisors (including attorneys and accountants) or to bona fide potential subcontractors or sublicensees who have entered into [***] with such Party that are subject to obligations of confidentiality and non-use at least as equivalent in scope as and no less restrictive than those set forth in this Article 15 prior to any such disclosure (but of shorter duration, if customary), in each case, in connection with the Target Program;

(i) disclosure pursuant to Section 15.5; and

(j) with respect to the Exclusively Licensed Proteovant [***] Technology and in connection with the exercise of Proteovant's rights under the Proteovant Research License, (A) disclosure by Proteovant to its Affiliates and its and their employees, and (B) disclosure by Proteovant to potential or actual research and development collaborators, subcontractors, sublicensees, advisors (including attorneys and accountants) or to bona fide potential subcontractors or sublicensees who have entered into [***] with Proteovant; provided that, in each case of (A) and (B), each disclosee is bound by obligations of confidentiality and non-use at least as equivalent in scope as and no less restrictive than those set forth in this Article 15 prior to any such disclosure (but of shorter duration, if customary).

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Sections 15.2(a), 15.2(c) or 15.2(e), it will, except where impracticable, (A) give reasonable advance notice to the other Party of such disclosure (including as to the form and terms of such disclosure), (B) give the other Party copies of any such disclosure, (C) give the other Party a reasonable opportunity to review and comment on any such disclosure (including the form and terms thereof) and consider such comments [***] and (D) use [***] efforts to secure confidential treatment of such information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder, except as permitted in this Section 15.2.

Nothing in Sections 15.1 or 15.2 will limit either Party in any way from disclosing to any Third Party such Party's U.S. or foreign income tax treatment and the U.S. or foreign income tax structure of the transactions relating to such Party that are based on or derived from this Agreement, as well as all materials of any kind (including opinions or other tax analyses) relating to such tax treatment or tax structure, except to the extent that nondisclosure of such matters is reasonably necessary in order to comply with applicable securities laws.

15.3 Publicity; Terms of Agreement.

(a) The Parties agree that the existence and terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in Section 15.2 and this Section 15.3. Except as set forth in Section 15.3(b) and 15.3(c), each Party agrees not to issue any press release or other public announcement disclosing the terms of this Agreement or the transaction contemplated hereby without the prior written consent of the other Party. Notwithstanding the foregoing, the Parties agree to issue a press release to announce

the execution of this Agreement in the form attached hereto as **Schedule 15.3(a)**, and thereafter, Proteovant and Blueprint may each disclose to Third Parties the information contained in such press release without the need for further approval by the other Party.

(b) In the case of a press release or governmental filing concerning the terms of this Agreement or the transaction contemplated hereby required by Applicable Law (where reasonably advised by the disclosing Party's counsel), the disclosing Party will give prior advance notice (to the extent it reasonably can) of the proposed text of such release or filing to the other Party for its prior review not later than [***] prior to such release or filing and will consider and incorporate [***] any comments provided by the other Party in connection therewith.

(c) The Parties acknowledge that either or both Parties may be obligated to file under Applicable Law a copy of this Agreement with the SEC or other Governmental Authorities. Each Party will be entitled to make such a required filing, provided that it requests confidential treatment of at least the financial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment not less than [***] (or a shorter period of time if required by Applicable Law) prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), and will reasonably consider the other Party's comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed, and will only disclose Confidential Information which it is advised by counsel or the applicable Governmental Authority is legally required to be disclosed. No such notice will be required under this Section 15.3(c) if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by either Party hereunder or otherwise approved by the other Party and such information remains accurate as of such time.

(d) Each Party will require each of its Affiliates to which Confidential Information of the other Party is disclosed as permitted hereunder to comply with the covenants and restrictions set forth in Sections 15.1 through Section 15.3 as if each such Affiliate were a Party to this Agreement and will be fully responsible for any breach of such covenants and restrictions by any such Affiliate.

15.4 Publications.

(a) Neither Party will publicly present or publish results of studies carried out under the applicable Research Plan for each Target Program (each such presentation or publication a "**Publication**") without the prior review and written approval by the other Party, except to the extent otherwise required by Applicable Law, in which case Section 15.3 will apply with respect to disclosures required by the SEC or for regulatory filings. From and after each Option Exercise Date, with respect to results of studies carried out outside of any Research Plan (i) Blueprint will have the sole right to publicly present or publish such results with respect to the applicable Licensed Compound and corresponding Licensed Products in its sole discretion (each such presentation or publication a "**Post-Option Publication**"), and (ii) Proteovant will have no right to publicly present or publish such results of such studies with respect to such Licensed

Compounds and corresponding Licensed Products without Blueprint's prior written approval; provided, that: (A) with respect to any proposed Post-Option Publication that discloses [***]; and (B) if Proteovant exercises its Opt-In Right with respect to an Eligible Opt-In Program, then, [***]. Notwithstanding anything to the contrary herein, if the proposed Post-Option Publication contains data of studies that have already been presented, Blueprint will have no obligation to provide such Post-Option Publication to Proteovant for review. [***].

(b) Nothing contained in this Section 15.4 will prohibit the inclusion of Confidential Information of the other Party in a patent application claiming or Covering the Manufacture, use, sale or formulation of a Collaboration Compound; provided that the non-filing Party is given an opportunity to review, comment upon and approve the information to be included prior to submission of such patent application, where and to the extent required by Article 12 hereof. Notwithstanding the foregoing, Blueprint will not have the right to publish or present Proteovant's Confidential Information without Proteovant's prior written consent, and Proteovant will not have the right to publish or present Blueprint's Confidential Information without Blueprint's prior written consent. Each Party agrees to acknowledge the contributions of the other Party, and the employees of the other Party, in all publications as scientifically appropriate. This Section 15.4 will not limit and will be subject to Section 15.5.

15.5 Publication and Listing of Clinical Trials and Compliance with other Policies, Orders and Agreements. The Parties agree to comply, with respect to the Collaboration Compounds and the corresponding Licensed Compounds and Licensed Product(s), with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, (b) any applicable court order, stipulations, consent agreements and settlements entered into by a Party, and (c) Blueprint's research and development policy concerning Clinical Trials registration and disclosure of results as amended from time to time and other Blueprint policies or other policies adopted by it for the majority of its other pharmaceutical products with regard to the same (to the extent the same are not in direct conflict with the documents referred to in clauses (a) and (b) above and, in the case of Proteovant, to the extent such policies are provided by Blueprint to Proteovant in writing prior to requiring their implementation under this Agreement).

15.6 Termination of Prior CDA. This Agreement terminates, as of the Effective Date, the Prior CDA. All Information exchanged between the Parties under the Prior CDA will be deemed Confidential Information of the corresponding Party under this Agreement and will be subject to the terms of this Article 15.

15.7 Residual Information. Notwithstanding anything to the contrary in this Agreement, the Parties will be free to use Residual Information to undertake the research, development, manufacture and commercialization of its own products and services and in support of the products and services of Affiliates and Third Parties with which such Party has a contractual obligation to do so, so long as such purpose does not conflict with the licenses granted to each Party hereunder or the restrictive covenants set forth in Article 14. Neither Party will, and will cause its employees, consultants and subcontractors performing such Party's obligations under this Agreement not to, reduce any Residual Information to writing in any manner. This Section 15.7 will not be deemed to authorize any use of any tangible or written embodiments of any Residual Information.

15.8 Security Measures.

(a) Each Party will, and will cause its Affiliates and its and their respective sublicensees, subcontractors (including, with respect to Proteovant, [***]) and other agents performing activities under this Agreement on such Party's behalf (collectively, the "**Performing Persons**"), to maintain reasonable safeguards and take technical, physical and organizational precautions to ensure the security, integrity and confidentiality of the other Party's Confidential Information, and ensure such information against destruction, loss, alteration, unauthorized access by or disclosure to Third Parties while in the possession or under the control of the Performing Persons. Neither Party nor such Party's Performing Persons will access electronic systems established or maintained by or on behalf of the other Party (the "**Systems**") other than as necessary to perform its obligations under this Agreement, and only through technical means mutually agreed by the Parties. Each Party will, and will cause its Performing Persons to, take reasonable measures to prevent improper access or an attempt to improperly access the other Party's Systems; or interference or an attempt to interfere with the proper functioning of the other Party's Systems or any activities conducted thereon; or bypass or circumvention of, or an attempt to bypass or circumvent, any measures the other Party (or its vendors, subcontractors or licensors) may use to prevent or restrict access to such Party's Systems. Each Party will at all times be responsible to the other Party for the compliance by such Party's Performing Persons with the security measures set forth in this Section 15.8(a).

(b) Each Party will, and will cause its Performing Persons to, implement and maintain reasonable and sufficient procedures to detect and respond to any actual or likely unauthorized access to, possession, disclosure or use of, or other security breaches involving, the other Party's Confidential Information that is on any System owned or managed by, or for the benefit of, such Party (such incident, a "**Security Incident**"). Each Party will promptly notify the other Party of any Security Incident when it suspects or becomes aware of it, including any material breach or potential material breach of security, on such Party's System which contains or processes such Confidential Information. Each Party will promptly furnish to the other Party relevant full details of the confirmed or suspected Security Incident, and use reasonable efforts to assist the other Party in investigating or preventing the recurrence of any Security Incident on such Party's System. Each Party will cooperate with the other Party to correct any Security Incident, and in any litigation and investigation to protect the other Party's proprietary rights. Each Party will use Commercially Reasonable Efforts to prevent a recurrence of any Security Incident.

16. TERM AND TERMINATION

16.1 Term. This Agreement will become effective on the Effective Date and, [***].

16.2 [***].

16.3 Termination by Either Party for Breach.

(a) Subject to Section 16.3(b), in the event that a Party materially breaches its obligations under this Agreement [***].

(b) If the alleged breaching Party disputes the existence or materiality of a breach specified in a Termination Notice provided by the other Party in accordance with

Section 16.3(a), and such alleged breaching Party provides the other Party notice of such dispute within the applicable Cure Period after receiving such Termination Notice, then the matter will be resolved as provided in Article 19 and the non-breaching Party will not have the right to terminate this Agreement under Section 16.3(a) unless and until such dispute has been submitted to arbitration in accordance with Article 19 and it has been finally determined under Section 19.2 that this Agreement has been materially breached, and the breaching Party fails to cure such breach within [***] following such arbitrators' decision under Section 19.2 (or if such breach cannot be cured within such [***] period, then such Cure Period will be extended for an additional [***]ys if the alleged breaching Party has commenced and [***] continues [***] to cure such breach, except to the extent such breach involves the failure to make a payment when due, which failure to make a payment must be cured within [***] following such arbitrators' decision). Except as provided in this Section 16.3(b), during the pendency of any such dispute, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder and the Cure Period set forth in Section 16.3(a) will be tolled from the date the breaching Party notifies the non-breaching Party of such dispute and through the resolution of such dispute in accordance with the applicable provisions of this Agreement.

16.4 Termination by Either Party for Insolvency. A Party will have the right to terminate this Agreement upon written notice if the other Party incurs an Insolvency Event; provided, however, in the case of any involuntary bankruptcy proceeding, such right to terminate will only become effective if the Party that incurs the Insolvency Event consents to the involuntary bankruptcy or if such proceeding is not dismissed or stayed within [***] after the filing thereof. "**Insolvency Event**" means circumstances under which a Party: (a) has a receiver or similar officer appointed over all or a material part of its assets or business; (b) passes a resolution for winding-up of all or a material part of its assets or business (other than a winding-up for the purpose of, or in connection with, any solvent amalgamation or reconstruction) or a court enters an order to that effect; (c) has entered against it an order for relief recognizing it as a debtor under any insolvency or bankruptcy laws (or any equivalent order in any jurisdiction); or (d) enters into any composition or arrangement with its creditors with respect to all or a material part of its assets or business (other than relating to a solvent restructuring).

16.5 Automatic Termination of a Target Program. If Blueprint does not deliver an Option Exercise Notice with respect to a Target Product prior to the expiration of the applicable Option Exercise Period, this Agreement will automatically terminate with respect to such Target Program and corresponding Collaboration Target.

16.6 Termination for Blueprint Patent Challenge. If Blueprint, its Affiliate or any Sublicensee challenges, under any court action or proceeding, or before any patent office, the validity, patentability or enforceability of any Royalty-Bearing Patent under this Agreement, or initiates a reexamination of any such Royalty-Bearing Patent, or assists any Third Party to conduct any of the foregoing activities (each, a "**Blueprint Patent Challenge**") and such Blueprint Patent Challenge [***], Proteovant may terminate this Agreement solely with respect to the Target Program (or Licensed Target Program, as applicable) to which such Patent Covers any Collaboration Compounds, Licensed Compounds or Licensed Products under such Target Program (or Licensed Target Program, as applicable) [***].

16.7 [***]:

16.8 Effects of Termination of this Agreement. Upon termination of this Agreement by a Party pursuant to Section 16.2 through 16.6, the following terms will apply to this Agreement, either in its entirety or with respect to the terminated Target Program or Licensed Target Program (each, a "**Terminated Program**") that is the subject of such termination, as the case may be:

(a) License.

(i) With respect to a Terminated Program, all licenses and rights granted by a Party to other Party with respect to the applicable Collaboration Compounds and the corresponding Licensed Compounds and Licensed Products will terminate; provided that, notwithstanding such termination, if Blueprint has exercised its Option with respect to the applicable Terminated Program, then any sublicense granted to a Sublicensee in accordance with Section 10.5 prior to the effective date of termination of this Agreement or the applicable Terminated Program will survive provided that such Sublicensee is not otherwise in breach of the terms of this Agreement to the extent applicable to such Sublicensee or engaged in a Blueprint Patent Challenge (in which event, such Person will be deemed a direct licensee of Proteovant) (each a "**Surviving Sublicense**"); provided, further, that any such Person will only be responsible for any payments that become due as a result solely of such Person's activities after the effective date of any such termination. For the avoidance of doubt, the duties and obligations of Proteovant with respect to any Surviving Sublicense will not be greater than the duties and obligations of Blueprint under this Agreement.

(ii) All licenses and rights granted by Blueprint to Proteovant with respect to any Blueprint Target Binder Compounds that relate to such Terminated Program will terminate except as otherwise provided under this Section 16.8.

(b) **Return of Confidential Information**. Within [***] after the effective date of termination, each Party will destroy all tangible items comprising, bearing or containing any Confidential Information of the other Party that are in its or its Affiliates' Control (except to the extent any information is the Confidential Information of both Parties or to the extent that it is necessary for the Receiving Party to have a continuing right to use the Confidential Information in accordance with the exercise of its rights or performance of its obligations under this Agreement post such termination); provided, that such Party may retain one (1) copy of such Confidential Information for its legal archives, and provided further that such Party will not be required to destroy electronic files containing Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information;

(c) **Accrued Payments**. Proteovant will remain entitled to receive all payments that accrued but were unpaid before the effective date of such termination;

(d) **Dissolution of Committees**. If this Agreement is terminated in its entirety, the JRC, JPT, JSC, JDC and JCC (and all Working Groups and committees) will be dissolved as of the effective date of such termination;

(e) **Survival**. Certain provisions herein will survive termination, in accordance with Section 16.12;

(f) **Reversion of Rights to Proteovant Prior to Option Exercise**. If this Agreement or a Target Program is terminated by Proteovant in accordance with Section 16.3, Section 16.4 or Section 16.6 or by Blueprint in accordance with Section 16.2, then with respect to the Reversion Compounds (but, excluding any Scheduled Blueprint Contributed Compound) and Reversion Products (but, excluding any product containing Scheduled Blueprint Contributed Compound) for such Terminated Program then being Researched as of the effective date of such termination, upon Proteovant's written request, for a period of [***] following such request, the Parties will negotiate [***] to enter into a license agreement on commercially reasonable and customary terms pursuant to which Blueprint would grant Proteovant [***] under the Blueprint Technology and Blueprint's interest in the Joint Know-How and Joint Patents, in each case, that exist as of the effective date of termination and actually used by Blueprint or its Affiliates as of the effective date of termination, to Research, Develop, Manufacture, Commercialize and otherwise Exploit such Reversion Compounds and Reversion Products under such Terminated Program in the Field in the Territory. In determining the commercially reasonable consideration for such license, on a Reversion Product-by-Reversion Product basis, the Parties will take into account [***].

(g) **Reversion of Rights to Proteovant After Option Exercise**. If this Agreement or a Licensed Target Program is terminated by Proteovant in accordance with Section 16.3, Section 16.4 or Section 16.6 or by Blueprint in accordance with Section 16.2, then with respect to the Reversion Compounds and Reversion Products for such Terminated Program then being Developed or Commercialized as of the effective date of such termination and, subject to any Surviving Sublicense and the terms of Section 16.8(a), the following terms and conditions will apply:

(i) Proteovant will have the sole right (and will solely control, at its discretion), itself or with or through its Affiliates, sublicensees or other Third Parties, to: (A) prepare and submit to applicable Regulatory Authorities any regulatory materials for such Reversion Compounds and Reversion Products; and (B) obtain and maintain Regulatory Approvals for such Reversion Compounds and Reversion Products;

(ii) Following the assignment of the Terminated Program Materials to Proteovant or its designees in accordance with Section 16.8(g)(iii): (A) Proteovant will have the exclusive right to correspond or communicate with Regulatory Authorities regarding such Reversion Compounds and Reversion Products; (B) unless required by Applicable Law, Blueprint, its Affiliates, Sublicensees and contractors will not correspond or communicate with Regulatory Authorities regarding any such Reversion Compounds and Reversion Products without first obtaining Proteovant's prior written consent (which approval will not be unreasonably withheld, delayed or conditioned); (C) and if Proteovant, its Affiliates, Sublicensees or contractors receive any correspondence or other communication from a Regulatory Authority regarding such Reversion Compounds and Reversion Products, Blueprint will provide Proteovant with access to or copies of such correspondence or other communication as soon as reasonably practicable after its receipt;

(iii) (A) Upon Proteovant's written request, Blueprint will assign and transfer to Proteovant all existing Regulatory Materials that are Controlled by Blueprint or its Affiliates and that solely relate to the Reversion Compounds and Reversion Products under such

Terminated Program ("**Terminated Program Materials**") within [***] after effective date of termination, and (B) to the extent assignment is delayed or not permitted by the applicable Regulatory Authority, Blueprint will grant and hereby grants to Proteovant and its designees a right of reference (without any further action required on the part of Blueprint or its Affiliates, whose authorization to file this right of reference with any Regulatory Authority is hereby granted) to any Terminated Program Materials and all data contained or referenced therein, solely for Proteovant and its designees to Develop and seek and maintain Regulatory Approvals of Reversion Compounds and Reversion Products under such Terminated Program;

(iv) If the Terminated Program is a Licensed Target Program, then Blueprint will assign to Proteovant, its and its Affiliates' rights, title and interest in the Product Patents that relate to the Reversion Compounds and Reversion Products under such Terminated Program that were assigned by Proteovant to Blueprint as of the IP Assignment Date in accordance with Section 12.1(c)(i).

(v) Any Licensed Compound Information and Joint Confidential Information for the Terminated Program with respect to the applicable Reversion Compound and Reversion Product will be deemed the Confidential Information of Proteovant (and not Blueprint or Blueprint and Proteovant, as applicable).

(vi) In consideration for the reversion rights provided to Proteovant pursuant to Section 16.8(g)(i) through Section 16.8(g)(v), inclusive, on a Terminated Program-by-Terminated Program basis, Proteovant will pay to Blueprint [***].

(vii) Upon Proteovant's written request, Blueprint will grant, and hereby grants as of the date the Parties agree on a [***] royalty rate (taking into account [***] in accordance with this Section 16.8(g)(vii), to Proteovant and its Affiliates an exclusive, worldwide, royalty-bearing, fully paid-up and sublicensable (through multiple tiers) license under the Blueprint Technology and Blueprint's interest in the Joint Know-How and Joint Patents, in each case, that exist as of the effective date of termination and are necessary or reasonably useful to Research, Develop, Manufacture, Commercialize and otherwise Exploit the Reversion Compounds and Reversion Products under such Terminated Program in the Field in the Territory. The applicable Patents will be listed on a schedule to be attached to the applicable definitive agreement to be promptly entered into by the Parties with respect to such Reversion Compounds and Reversion Products.

(h) **Wind-Down of Clinical Trials**. If the Terminated Program is a Licensed Target Program, and if, as of the effective date of termination, Blueprint or its Affiliates or Sublicensees are conducting any Clinical Trials for the applicable Licensed Products, then the Parties will [***] discuss and agree upon the appropriate completion or wind-down of such Clinical Trials, subject to Applicable Law. The Parties will [***] to wind-down such Clinical Trials; provided, that if this Agreement or the relevant Terminated Program is terminated for any reason other than a termination by Blueprint in accordance with Section 16.3 or Section 16.4, then upon Proteovant's written request, Blueprint will transfer such Clinical Trials to Proteovant or its designee and Blueprint will continue such Clinical Trials, [***] until such transfer is completed; provided, further that each Party will cooperate [***] to enable the expeditious transfer of such

Clinical Trials, and Proteovant will assume any and all liability for the conduct of such transferred Clinical Trials after the effective date of transfer.

16.9 Inventory.

(a) If this Agreement or a Licensed Target Program is terminated for any reason other than a termination by Proteovant in accordance with Section 16.3, Section 16.4 or Section 16.6, then Blueprint will be entitled to sell any inventory of Licensed Product as of the effective date of the termination. Blueprint will pay Proteovant the amounts applicable to such sales in accordance with the terms and conditions of this Agreement.

(b) If this Agreement or a Licensed Target Program is terminated by Proteovant in accordance with Section 16.3, Section 16.4 or Section 16.6 or by Blueprint in accordance with Section 16.2, then at any time within [***] after the effective date of termination with respect to a Reversion Product, [***]

16.10 Effects of Expiration of Agreement. Upon the expiration of the Royalty Term (i.e., in the case where there is no earlier termination pursuant to this Article 16), on a Licensed Product-by-Licensed Product and country-by-country basis, the license granted to Blueprint under Section 10.1(b) will convert to a fully paid-up, perpetual and irrevocable license; provided that such license during the applicable Opt-In Term will not convert with respect to the Opt-In Territory to the extent such Licensed Product is an Opt-In Product. Certain provisions herein will survive expiration, in accordance with Section 16.12.

16.11 Other Remedies. Except as otherwise provided in this Article 16, expiration or earlier termination of this Agreement for any reason will not release either Party from any liability or obligation (including payments) that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Subject to and without limiting the terms and conditions of this Agreement (including Section 18.4), expiration or termination of this Agreement will not preclude any Party from (a) claiming any other damages, compensation or relief that it may be entitled to upon such expiration or termination, (b) any right to receive any amounts accrued under this Agreement prior to the expiration or termination date but which are unpaid or become payable thereafter and (c) any right to obtain performance of any obligation provided for in this Agreement which will survive expiration or termination.

16.12 Survival. Termination or expiration of this Agreement will not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration of this Agreement. Notwithstanding anything to the contrary, the following provisions will survive and apply after expiration or termination of this Agreement: Article 1 (Definitions), Article 11 (Payments) (solely with respect to payment obligations accrued prior to the date of termination or expiration), Article 15 (Confidentiality) (for the time period set forth therein), Article 18 (Indemnification) (excluding Section 18.5), Article 19 (Dispute Resolution), Article 20 (Miscellaneous) (excluding Section 20.7 and Section 20.12), the first sentence of Section 2.9(c) (Materials Transfer), Section 12.1 (Ownership of Information and Inventions), Section 12.5 (CREATE Act), Section 13.1 (Licensed Product Trademarks), Section 16.8 (Effects of Termination of this Agreement), Section 16.9 (Inventory), Section 16.10 (Effects of Expiration

of Agreement) (solely in the event of expiration of this Agreement), Section 16.11 (Other Remedies), this Section 16.12 (Survival), and Section 17.4 (No Other Representations or Warranties). If this Agreement is terminated with respect to one or more Target Programs or Licensed Target Programs but not in its entirety, then following such termination the foregoing provisions of this Agreement will remain in effect with respect to such terminated Target Programs or Licensed Target Programs (to the extent they would survive and apply in the event the Agreement expires or is terminated in its entirety), and all provisions not surviving in accordance with the foregoing will terminate upon termination of this Agreement with respect to the applicable Target Programs or Licensed Target Programs and be of no further force and effect.

All provisions not surviving in accordance with the foregoing will terminate upon expiration or termination of this Agreement and be of no further force and effect.

17. REPRESENTATIONS AND WARRANTIES

17.1 Mutual Representations, Warranties, and Covenants. Each Party hereby represents and warrants to the other Party as of the Effective Date and, where denoted below, covenants to the other Party as follows:

(a) It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

(b) It has the full corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder. It has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) It is not a party to any agreement, outstanding order, judgment or decree of any court or Governmental Authority that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement.

(d) In the course of conducting Research and Development of Collaboration Compounds and the corresponding Licensed Compounds and Licensed Products or Medical Affairs activities in support of such Research and Development, such Party has not used prior to the Effective Date and will not use, during the Term, any employee, agent or independent contractor who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Upon request by a Party and subject to Applicable Laws, the other Party agrees to provide a list of persons, including Third Parties, used to perform the services or work provided under any activities conducted for or on behalf of such Party or any of its Affiliates pursuant to this Agreement who, within the [***] preceding the Effective Date, or subsequent to the Effective Date, were or are convicted of one of

the criminal offenses enumerated in section 306 of the FD&C Act, as amended, or subject to similar sanction of any other Regulatory Authority.

(e) It has not, and will not, after the Effective Date and during the Term, grant any right to any Third Party that would conflict with the rights granted to the other Party hereunder.

(f) In the course of performing its obligations or exercising its rights under this Agreement, it will, and will cause its Affiliates, licensees or sublicensees, and subcontractors to comply with the Research Plan and all Applicable Laws, including as applicable, GLP standards.

(g) Each Party will promptly provide the other Party with written notice upon becoming aware of any breach or violation by a Party or its Affiliates of any representation, warranty or undertaking set forth in this Section 17.1.

17.2 Representations, Warranties, and Covenants by Proteovant. Except as set forth on **Schedule 17.2** attached hereto, which Schedule may be updated by Proteovant [***] (each such date, a "**Proteovant Disclosure Date**") to include any exceptions to the representations and warranties set forth below solely to the extent such exceptions arise following the last delivery to Blueprint of such Schedule, [***], Proteovant hereby represents and warrants as of the Effective Date, and with respect to each Collaboration Compound, as of the corresponding Proteovant Disclosure Date (unless otherwise denoted below), to Blueprint as follows:

(a) The Proteovant Technology is free and clear from any Liens, and Proteovant has sufficient legal or beneficial title, ownership or license thereunder to grant the licenses and ownerships to Blueprint as purported to be granted pursuant to this Agreement. Proteovant is the sole owner of all right, title and interest in and to (free and clear from any Liens of any kind) the Proteovant Patents and Proteovant [***] Patents that are Controlled by Proteovant or its Affiliates (the "**Existing Proteovant Patents**"). All fees required to maintain the Existing Proteovant Patents have been paid to date, the pending applications included in the Existing Proteovant Patents are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law. The Existing Proteovant Patents constitute all Patents Controlled by Proteovant or, subject to Section 20.9(b), its Affiliates, that are necessary or reasonably useful to Research, Develop, make, have made, Manufacture, use, sell, offer for sale, import, export or Commercialize Collaboration Compounds and the corresponding Licensed Compounds and Licensed Products, and there are no intellectual property rights of the Excluded Affiliates that are necessary or reasonably useful to Research, Develop, make, have made, Manufacture, use, sell, offer for sale, import, export or Commercialize Collaboration Compounds and the corresponding Licensed Compounds and Licensed Products. With respect to a given Licensed Target Program, as of the Option Exercise Date for such Target Program, other than rights that Blueprint may have with respect to a Licensed Compound under such Licensed Target Program or any Intellectual Property Rights related thereto, Proteovant is the sole owner of any Existing Proteovant Patent that Covers such Licensed Compound or the existing Proteovant Know-How and Proteovant [***] Know-How for such Licensed Compound.

(b) Proteovant has not entered into any written agreements with any Third Party under which Proteovant has obtained a license or sublicense of rights from a Third Party to any Collaboration Compound that requires a license or sublicense to Blueprint under this Agreement.

(c) Proteovant has not received any written notice from any Third Party asserting or alleging that the discovery, Research or Development of the Collaboration Compounds by Proteovant infringes the Intellectual Property Rights of such Third Party.

(d) To Proteovant's Knowledge, the discovery, Research and Development of Collaboration Compounds by or on behalf of Proteovant has not infringed or misappropriated any Patents or proprietary Information owned or controlled by a Third Party.

(e) There are no pending, and, to Proteovant's Knowledge, no threatened, actions, suits or proceedings against Proteovant involving the Proteovant Technology as it relates to the Target Program or any Collaboration Compound, and to Proteovant's Knowledge there are no (i) inter partes reviews, post-grant reviews, interferences, re-examinations or oppositions involving the Existing Proteovant Patents that are in or before any patent authority (or other Governmental Authority performing similar functions) or (ii) any inventorship challenges involving the Existing Proteovant Patents that are in or before any patent or other Governmental Authority.

(f) Proteovant is not aware of any Third Party that is infringing or has infringed or misappropriated the Proteovant Technology as it relates to the applicable Target Program.

(g) No claim has been issued or served, or written threat of a claim or litigation made by any Person, against Proteovant that alleges that any issued Existing Proteovant Patents are invalid or unenforceable.

(h) Proteovant has not granted any license or any option for a license under, or any right, title or interest in or to, the Proteovant Technology to any Third Party to Research, Develop, Manufacture, Commercialize or otherwise Exploit any Collaboration Compound, in any country in the Territory that conflicts with the licenses and options for a license granted by Proteovant to Blueprint under this Agreement.

(i) No person, other than former or current employees or consultants of Proteovant who are obligated in writing to assign his/her inventions to Proteovant, is an inventor of any of the inventions claimed in the Existing Proteovant Patents or, as of the corresponding Proteovant Disclosure Date, Proteovant's interest in the existing Joint Patents. All inventors of any inventions included within the Existing Proteovant Patents or, as of the corresponding Proteovant Disclosure Date, Proteovant's interest in the existing Joint Patents have assigned or have a contractual obligation to assign or license their entire right, title and interest in and to such inventions and the corresponding Existing Proteovant Patents or, as of the corresponding Proteovant Disclosure Date, Proteovant's interest in the existing Joint Patents to Proteovant or its Affiliates. To Proteovant's Knowledge, no current or former employee or consultant of Proteovant owns or has any proprietary, financial or other interest, direct or indirect, in the Existing Proteovant Patents or, as of the corresponding Proteovant Disclosure Date, Proteovant's interest in the existing Joint Patents. To Proteovant's Knowledge, there are no claims that have been asserted in writing challenging the inventorship of the Existing Proteovant Patents or, as of the corresponding Proteovant Disclosure Date, Proteovant's interest in the existing Joint Patents.

(j) The inventions claimed in the Existing Proteovant Patents or, as of the corresponding Proteovant Disclosure Date, Proteovant's interest in the existing Joint Patents were not conceived, reduced to practice, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by any grants, funds, and other money received from any Governmental Authority, and no Governmental Authority or academic institution has any right to, ownership of (including any "step-in" or "march-in" rights with respect to), or right to royalties for, or to impose any restriction on the assignment, transfer, grant of licenses or other disposal of the Existing Proteovant Patents or the existing Proteovant Know-How or Proteovant [***] Know-How, as of the corresponding Proteovant Disclosure Date, Proteovant's interest in the existing Joint Patents, or to impose any requirement or restriction on the Exploitation or manufacture of any Collaboration Compound, as contemplated herein.

(k) As of the date Proteovant presents any Collaboration Compound to Blueprint in accordance with Section 2.3(b), 2.3(c) and 2.3(d) and, in the event Blueprint exercised the appliable Option, as of the date Blueprint exercises such Option, (i) Proteovant or, subject to Section 20.9(b), its Affiliates, will Control any Existing Proteovant Patent and Proteovant's interest in the existing Joint Patents that Covers any such Collaboration Compound or the existing Proteovant Know-How or Proteovant [***] Know-How for such Collaboration Compound, (ii) to Proteovant's Knowledge, the discovery, research, or Development of any such Collaboration Compound by or on behalf of Proteovant has not infringed or misappropriated any Patents or proprietary Information owned or controlled by a Third Party; and (iii) no claim or action has been brought against Proteovant or, to Proteovant's Knowledge, threatened in writing to Proteovant, by any Third Party alleging that the use of any such Collaboration Compound as contemplated under this Agreement infringes the Patents or misappropriates the Information of any Third Party.

(l) [***].

17.3 Representations, Warranties, and Covenants by Blueprint. With respect to an Eligible Opt-In Program, except as set forth in **Schedule 17.3**, attached hereto, which Schedule may be updated by Blueprint within the [***] period immediately following the latest of: (i) [***], (ii) [***], and (iii) t[***], the "**Blueprint Disclosure Date**") to include any exceptions to the representations and warranties set forth below, Blueprint hereby represents and warrants on the applicable Blueprint Disclosure Date with respect to [***] for such Eligible Opt-In Program to Proteovant as follows:

(a) The Blueprint Target Binder Compound Technology is free and clear from any Liens. Blueprint is the sole owner of all right, title and interest in and to (free and clear from any Liens of any kind), the existing Blueprint Target Binder Compound Patents (the "**Existing Blueprint Patents**"). All fees required to maintain the existing Blueprint Patents have been paid to date, and the pending applications included in Blueprint Target Binder Compound Patents are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law.

(b) Blueprint has not received any written notice from any Third Party asserting or alleging that the discovery, Research or Development of the Blueprint Target Binder Compound by Blueprint infringes the Intellectual Property Rights of such Third Party.

(c) There are no pending, and, to Blueprint's Knowledge, no threatened, (i) actions, suits or proceedings against Blueprint involving the Blueprint Target Binder Compound Patents as it relates to the Target Program, or any Collaboration Compounds, (ii) inter partes reviews, post-grant reviews, interferences, re-examinations or oppositions involving the Existing Blueprint Patents that are in or before any patent authority (or other Governmental Authority performing similar functions) or (iii) any inventorship challenges involving the Existing Blueprint Patents that are in or before any patent or other Governmental Authority.

(d) Blueprint is not aware of any Third Party that is infringing or has infringed or misappropriated any Blueprint Target Binder Compound Technology as it relates to the Target Program.

17.4 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 17, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, OR THAT ANY OF THE DEVELOPMENT OR COMMERCIALIZATION EFFORTS WITH REGARD TO ANY COMPOUND OR PRODUCT WILL BE SUCCESSFUL, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

18. INDEMNIFICATION AND LIMITATION OF LIABILITY

18.1 Indemnification by Proteovant for Third Party Claims. Proteovant will defend, indemnify, and hold Blueprint, its Affiliates, and its and their respective officers, directors, employees, and agents (collectively, the "**Blueprint Indemnitees**") harmless from and against any and all damages, losses, liabilities, or other amounts payable to a Third Party, as well as any reasonable attorneys' fees and costs of litigation incurred by such Blueprint Indemnitees, all to the extent arising out of or resulting from any claims, suits, proceedings or causes of action brought by such Third Party (collectively, "**Blueprint Claims**") against such Blueprint Indemnitee that arise out of or result from: (a) a breach of any of Proteovant's representations, warranties, covenants and obligations under this Agreement; (b) the gross negligence, recklessness or willful misconduct of or violation of Applicable Law by any Proteovant Indemnitees or their licensees, sublicensees or subcontractors in connection with this Agreement; or (c) the Research, Development, or other Exploitation of Collaboration Compounds, Opt-In Compounds, or Opt-In Products (other than Product Liability Costs related to an Opt-In Compound or an Opt-In Product) in the Field in the Territory by or on behalf of Proteovant, its Affiliates, or its or their licensees, sublicensees or subcontractors before the Effective Date or during the Term. The foregoing indemnity obligation will not apply to the extent that any Blueprint Claim is subject to indemnity pursuant to Section 18.2.

18.2 Indemnification by Blueprint for Third Party Claims. Blueprint will defend, indemnify, and hold Proteovant, its Affiliates, and its and their respective officers, directors, employees, and agents (collectively, the "**Proteovant Indemnitees**") harmless from and against any and all damages, losses, liabilities, or other amounts payable to a Third Party, including any

fines imposed by a Governmental Authority, as well as any reasonable attorneys' fees and costs of litigation incurred by such Proteovant Indemnitees, all to the extent arising out of or resulting from any claims, suits, proceedings or causes of action brought by such Third Party (collectively, "**Proteovant Claims**") against such Proteovant Indemnitee that arise out of or result from: (a) the Research, Development, Manufacture, Commercialization, storage, handling, use, sale, offer for sale, exportation or importation, and other Exploitation of any Collaboration Compounds, Licensed Compounds (including Opt-In Compounds), or Licensed Products (including Opt-In Products) (other than Product Liability Costs related to an Opt-In Compound or an Opt-In Product) in the Field in the Territory by or on behalf of Blueprint or its Sublicensees and its and their Affiliates during the Term; (b) a breach of any of Blueprint's representations, warranties, covenants and obligations under this Agreement; (c) the gross negligence, recklessness or willful misconduct of or violation of Applicable Law by any Blueprint Indemnitees or their licensees, sublicensees or subcontractors in connection with this Agreement; or (d) Blueprint's determination that a filing or notification is not necessary or advisable under any applicable Antitrust Law if Blueprint were to exercise the respective Option pursuant to this Agreement (except to the extent such determination was based on Proteovant's fraud or inaccurate information provided by Proteovant). The foregoing indemnity obligation will not apply to the extent that any Proteovant Claim is subject to indemnity pursuant to Section 18.1. Further, it is understood and agreed that the [***] are not agents for purposes of this Section 18.2.

18.3 Indemnification Procedures. The Party claiming indemnity under this Article 18 (the "**Indemnified Party**") will give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of the claim, suit, proceeding or cause of action for which indemnity is being sought ("**Claim**") (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a Claim will not affect the indemnification provided hereunder except to the extent the Indemnifying Party will have been prejudiced as a result of such failure or delay to give such notice), and, provided that the Indemnifying Party is not contesting the indemnity obligation, will permit the Indemnifying Party to control and assume the defense of any litigation relating to such claim and disposition of any such Claim unless the Indemnifying Party is also a party (or likely to be named a party) to the proceeding in which such claim is made and the Indemnified Party gives notice to the Indemnifying Party that it may have defenses to such claim or proceeding that are in conflict with the interests of the Indemnifying Party, in which case the Indemnifying Party will not be so entitled to assume the defense of the case. If the Indemnifying Party does assume the defense of any Claim, it (a) will act diligently [***] with respect to all matters relating to the settlement or disposition of any Claim as the settlement or disposition relates to Parties being indemnified under this Article 18, (b) will cause such defense to be conducted by counsel reasonably acceptable to the Indemnified Party and (c) will not settle, admit liability or otherwise resolve any Claim without prior notice to the Indemnified Party and the consent of the Indemnified Party (such consent not to be unreasonably conditioned, withheld or delayed) if such settlement involves anything other than the payment of money by the Indemnifying Party (including, for example, any settlement admitting fault or wrongdoing of the Indemnified Party, or consenting to any injunctive relief). The Indemnified Party will reasonably cooperate with the Indemnifying Party in its defense of any claim for which the Indemnifying Party has assumed the defense in accordance with this Section 18.3, and will have the right, at its own cost and expense, to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification; provided, however, that, the Indemnifying Party will pay such costs and expenses of the Indemnified Party if (x) the

employment thereof has been specifically authorized in writing by the Indemnifying Party, (y) the Indemnifying Party has failed to assume the defense and employ counsel and the Indemnified Party controls the defense in accordance with this Section 18.3 or (z) the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such Claim such that the representation by the same counsel of both Parties and any respective Indemnified Parties is prohibited under Applicable Law, ethical rules or equitable principles. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (i) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (ii) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this Article 18.

18.4 Limitation of Liability. EXCEPT FOR (A) INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION PURSUANT TO SECTION 18.1 OR 18.2 HEREUNDER, (B) A BREACH OF SECTION 10.1, SECTION 10.2, OR ARTICLE 14, (C) ANY BREACH OF ARTICLE 15 BY A PARTY OR ITS AFFILIATES OR ITS OR THEIR LICENSEES OR SUBLICENSEES AND THEIR AFFILIATES, OR (D) DAMAGES THAT ARE DUE TO THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF THE LIABLE PARTY IN CONNECTION WITH THIS AGREEMENT, IN NO EVENT WILL EITHER PARTY, ITS DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT, IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

18.5 Insurance. Each Party will maintain a program of insurance sufficient to fulfill its obligations under this Agreement, including product liability insurance, with respect to its Target Program activities and other obligations to be performed hereunder and which are consistent with normal business practices of prudent companies similarly situated to such Party at all times during which any Licensed Compound or corresponding Licensed Compound and Licensed Product(s) is being clinically tested in human subjects or commercially distributed or sold. It is understood that such insurance will not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 18. Each Party will provide the other Party with written evidence of such insurance upon request, which evidence will be treated as the providing Party's Confidential Information. Each Party will provide the other Party with written notice at least [***] prior to the cancellation, non-renewal or material adverse change in such insurance.

19. DISPUTE RESOLUTION

19.1 Disputes; Resolution by Executive Officers. The Parties recognize that disputes as to certain matters may from time to time arise during the Term that relate to decisions to be

made by the Parties herein or to the Parties' respective rights or obligations hereunder (a "**Dispute**"). It is the desire of the Parties to establish procedures to facilitate the resolution of Disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to arbitration or litigation. To accomplish this objective, except [***] in accordance with Article 9 or matters relating to patent and trademark disputes in accordance with Section 19.11, the Parties agree to follow the procedures set forth in this Article 19 if and when a Dispute arises under this Agreement, subject to Section 19.7.

19.2 Escalation to Executive Officers. In the event the Parties are unable to resolve a Dispute after [***] attempts to reach agreement over [***], then either Party may, by written notice to the other, have such issue referred to the Executive Officers for resolution. If the Executive Officers are unable to resolve the matter within [***], or such other longer time the Executive Officers may otherwise agree upon, after the matter is referred to them, then either Party may refer such issue to arbitration under Section 19.3 by providing written notice thereof to the other Party.

19.3 Long Form Arbitration. Any Dispute that is not resolved pursuant to Section 19.2, will be resolved solely and exclusively by binding arbitration to be conducted as set forth below in this Section 19.3.

(a) In any proceeding under this Section 19.3, there will be three (3) arbitrators. Within [***] after delivery of such notice, each Party will nominate one arbitrator in accordance with the then current rules of the AAA. The two arbitrators so nominated will nominate a third arbitrator to serve as chair of the arbitration tribunal, such nomination to be made within [***] after the selection of the second arbitrator. The arbitrators will be neutral and independent of both Parties and all of their respective Affiliates, will have significant experience and expertise in licensing and partnering agreements in the pharmaceutical and biotechnology industries, will have appropriate experience with respect to the matter(s) to be arbitrated, and will have some experience in mediating or arbitrating issues relating to such agreements. In the case of any dispute involving an alleged failure to use Commercially Reasonable Efforts, each arbitrator will in addition be an individual with experience and expertise in the worldwide development and commercialization of pharmaceuticals and the business, legal and scientific considerations related thereto. In the case of a dispute involving a scientific or accounting matter or determination, an Expert having applicable expertise and experience will be selected by the Parties to assist the arbitrators in such scientific or accounting matter or determination (and the arbitrators will select such Expert if the Parties cannot agree on such Expert within [***] following the selection of the arbitrators). The governing law in Section 20.10 will govern such proceedings. No individual will be appointed to arbitrate a dispute pursuant to this Agreement unless he or she agrees in writing to be bound by the provisions of this Section 19.3. The place of arbitration will be New York, New York, unless otherwise agreed to by the Parties, and the arbitration will be conducted in English.

(b) The arbitrators will set a date for a hearing that will be held no later than [***] following the appointment of the last of such three arbitrators. The Parties will have the right to be represented by counsel. Except as provided herein, the arbitration will be governed by the commercial arbitration rules of the AAA (the "**Commercial Arbitration Rules**") applicable at the time of the notice of arbitration pursuant to Section 19.2, including the right of each Party to undertake document requests.

(c) The arbitrators' decision and award will be made and delivered within [***] after completion of the hearing described in Section 19.3(b). The determination of the arbitrators as to the resolution of any dispute will be binding and conclusive upon the Parties. All rulings of the arbitrators will be in writing and will be delivered to the Parties as soon as is reasonably possible. Nothing contained herein will be construed to permit the arbitrators to award punitive, exemplary or any similar damages. The arbitrators will render a "reasoned decision" within the meaning of the Commercial Arbitration Rules which will include findings of fact and conclusions of law. Any arbitration award may be entered in and enforced by a court in accordance with Section 19.5 and Section 19.11. The Parties agree that the Federal Arbitration Act will apply to the arbitration and any arbitral award.

19.4 Expedited Arbitration. If the Parties (and the Executive Officers) are unable to agree on the terms of a Co-Commercialization Agreement in accordance with Section 7.4(b), such disagreement will be resolved solely and exclusively by binding arbitration to be conducted as set forth below in this Section 19.4 ("**Expedited Arbitration**").

(a) In any proceeding under this Section 19.4, there will be one (1) arbitrator selected by mutual agreement or, if the Parties are unable to agree on an arbitrator within [***] after such matter is referred to Expedited Arbitration, the Parties will request that AAA select the arbitrator, in each case satisfying the criteria set forth in Section 19.3(a) to the maximum extent possible.

(b) Within [***] after appointment of the arbitrator, each Party will submit to the arbitrator its proposed Co-Commercialization Agreement and a written memorandum of no more than fifteen (15) pages in support thereof (the "**Opening Brief**"). The arbitrator will provide each Party's Opening Brief to the other Party after he or she receives the Opening Brief from both Parties. Within [***] after a Party receives the other Party's Opening Brief from the arbitrator, such receiving Party will have the right to submit to the arbitrator a response to the other Party's Opening Brief (each, a "**Response Brief**") which will not exceed [***] in total. The arbitrator will provide each Party's Response Brief to the other Party after he or she receives a Response Brief from both Parties (or at the expiration of such [***] period if any Party fails to submit a Response Brief).

(c) There will be no discovery in the Expedited Arbitration (e.g., document requests, interrogatories, depositions, etc.). The arbitrator will, however, have the right to perform independent research and analysis and to request any Party provide additional documentary evidence that was Controlled by such Party prior to the arbitrator making such request.

(d) The arbitrator will be instructed to select one Party's proposal no later than [***] following the receipt of both Parties' Response Briefs (or expiration of the aforementioned [***] period if any Party fails to submit a Response Brief) and to select the proposal that he or she determines is the most commercially reasonable under the circumstances and best gives effect to the intent of the Parties under this Agreement. The arbitrator will accept only one of the proposals submitted by the Parties (without making any changes to such proposal) and will render such proposal as the arbitrator's final decision. Notwithstanding anything to the contrary in this Agreement, the arbitrator will not have the authority to render any decision other than selecting

one proposal submitted by a Party pursuant to this Section 19.4. The arbitrator's decision will be final and binding on the Parties.

19.5 Award. Any award to be paid by one Party to the other Party as determined by the arbitrators as set forth above under Section 19.3 will be promptly paid in Dollars free of any tax, deduction or offset, unless otherwise required by Applicable Law; and any costs, fees or taxes incident to enforcing the award will, to the maximum extent permitted by law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 19, and agrees that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in a court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award. Each Party consents to the jurisdiction of any federal court located in New York City, New York, or, if such federal court lacks jurisdiction, any state court of New York located in New York City, for the purpose of enforcing the arbitration provisions of this Agreement and enforcing any arbitrator's award; provided, however, that to the extent necessary to avoid irreparable harm, any party may seek temporary or preliminary injunctive relief in accordance with Section 19.8 in any court of competent jurisdiction. With respect to money damages, nothing contained herein will be construed to permit the arbitrators or any court or any other forum to award punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for punitive or exemplary damages. The only damages recoverable under this Agreement are compensatory damages.

19.6 Costs. Each Party will bear its own legal fees in connection with any arbitration procedure. The arbitrators conducting an arbitration under Section 19.3 may in their discretion assess the arbitrators' cost, fees and expenses (and those any Expert hired by the arbitrators) against the Party losing the arbitration.

19.7 WAIVER OF JURY TRIAL. EXCEPT AS LIMITED BY APPLICABLE LAW, EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED IN CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF ANY PARTY HERETO IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT HEREOF.

19.8 Injunctive Relief. Nothing in this Article 19 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. For the avoidance of doubt, nothing in this Section 19.8 will otherwise limit a breaching Party's opportunity to cure a material breach as permitted in accordance with Section 16.3 or Section 16.4. No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.

19.9 Confidentiality. The arbitration proceeding will be confidential and the arbitrators will issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by Applicable Law, no Party will make (or instruct the arbitrators to make) any public

announcement with respect to the proceedings or decision of the arbitrators without prior written consent of the other Party (which consent will not be unreasonably withheld, delayed or conditioned). The existence of any dispute submitted to arbitration, and any award, will be kept in confidence by the Parties and the arbitrators, except as required in connection with the enforcement of such award or as otherwise required by Applicable Law. Notwithstanding the foregoing, each Party will have the right to disclose information regarding the arbitration proceeding to the same extent as it may disclose Confidential Information of the other Party under Article 15 above.

19.10 Survivability. Any duty to arbitrate under this Agreement will remain in effect and be enforceable after termination of this Agreement for any reason.

19.11 Patent and Trademark Disputes. Notwithstanding Section 19.3, any dispute, controversy or claim relating to the inventorship, scope, validity, enforceability or infringement of any Patents Covering the Manufacture, use, importation, offer for sale or sale of Collaboration Compounds or the corresponding Licensed Compounds and Licensed Products or of any Product Marks will be submitted to a court of competent jurisdiction in the country in which such patent or trademark rights were granted or arose.

20. MISCELLANEOUS

20.1 Entire Agreement; Amendments. This Agreement, including the Exhibits hereto (which are incorporated into and made a part of this Agreement), sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including the Prior CDA. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to the subject matter hereof other than as are set forth herein. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized representative of each Party.

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

20.3 Rights in Bankruptcy.

(a) All rights and licenses granted under or pursuant to this Agreement by one Party to the other are, for all purposes of Section 365(n) of Title 11 of the U.S. Code ("**Title 11**"), licenses of rights to "intellectual property" as defined in Title 11, and, in the event that a case under Title 11 is commenced by or against either Party (the "**Bankrupt Party**"), the other Party, to the extent as a licensee of such rights under this Agreement, will have all of the rights set forth in Section 365(n) of Title 11 to the maximum extent permitted thereby. During the Term, each Party

will create and maintain current copies to the extent practicable of all such intellectual property licensed to such Party hereunder. Without limiting the Parties' rights under Section 365(n) of Title 11, if a case under Title 11 is commenced by or against the Bankrupt Party, the other Party will be entitled to a copy of any and all such intellectual property licensed to such Party hereunder and all embodiments of such intellectual property, and the same, if not in the possession of such other Party, will be promptly delivered to it (i) before this Agreement is rejected by or on behalf of the Bankrupt Party, within [***] after the other Party's written request, unless the Bankrupt Party, or its trustee or receiver, elects within [***] to continue to perform all of its obligations under this Agreement, or (ii) after any rejection of this Agreement by or on behalf of the Bankrupt Party, if not previously delivered as provided under clause (i) above. All rights of the Parties under this Section 20.3 and under Section 365(n) of Title 11 are in addition to and not in substitution of any and all other rights, powers, and remedies that each Party may have under this Agreement, Title 11, and any other Applicable Law.

(b) Any intellectual property provided pursuant to the provisions of this Section 20.3 will be subject to the licenses set forth elsewhere in this Agreement.

(c) In the event that after the Effective Date Proteovant enters into a license agreement with a Third Party with respect to intellectual property that will be sublicensed to Blueprint hereunder, Proteovant will use Commercially Reasonable Efforts to enable Blueprint to receive a direct license from any such Third Party in the event that such license agreement between Proteovant and such Third Party is terminated or rejected under Section 365(a) of Title 11 during the Term solely on account of Proteovant becoming a Bankrupt Party.

(d) Notwithstanding anything to the contrary in Article 12, in the event that Proteovant is the Bankrupt Party, Blueprint may take appropriate actions in connection with the filing, prosecution, maintenance and enforcement of any Joint Patents under this Agreement without being required to consult with Proteovant before taking any such actions, provided that such actions are consistent with this Agreement.

20.4 Force Majeure. Each Party will be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (defined below) and the nonperforming Party promptly provides notice of such prevention to the other Party. Such excuse will be continued so long as the condition constituting force majeure continues provided that the Party affected by such force majeure will take reasonable efforts to remove the condition constituting such force majeure. The Party affected by such force majeure also will notify the other Party of the anticipated duration of such force majeure and any actions being taken to avoid or minimize its effect after such occurrence. For purposes of this Agreement, "**force majeure**" will include conditions beyond the reasonable control of the Parties, including an act of God, acts of terrorism, voluntary or involuntary compliance with any regulation, law or order of any government, war, acts of war (whether war be declared or not), labor strike or lockout, civil commotion, epidemic or pandemic arising after the Effective Date or any material worsening of the ongoing COVID-19 pandemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe; provided, however, that the affected Party promptly notifies the other Party in writing stating the nature of the cause of non-performance, its anticipated duration and any action being taken to avoid or minimize its effect. The affected Party will use its Commercially Reasonable Efforts to

avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and will continue performance in accordance with the terms of this Agreement whenever such causes are removed. The nonperforming Party will promptly provide notice of such resumed performance to the other Party. The payment of invoices due and owing hereunder will in no event be delayed by the payer because of a force majeure affecting the payer, unless such force majeure itself prevents the payment.

20.5 Notices. Any notice required or permitted to be given under this Agreement will be in writing, will specifically refer to this Agreement, and will be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 20.5, in each case, accompanied by a courtesy copy email (which will not constitute notice) stating the same, and will be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable international expedited delivery service, or (b) [***] after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested. This Section 20.5 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

For Blueprint:	Blueprint Medicines Corporation 45 Sidney Street Cambridge, MA 02139 United States Attention: Chief Executive Officer
With a copy to: (which will not constitute notice)	Blueprint Medicines Corporation 45 Sidney Street Cambridge, MA 02139 United States Attention: Chief Legal Officer Email: [***]
For Proteovant:	Proteovant Therapeutics, Inc. 151 W 42nd St. 15th Floor New York, NY 10036 Attention: Chief Executive Officer Email: [***]
With a copy to: (which will not constitute notice)	Sidley Austin LLP 2850 Quarry Lake Drive, Suite 301 Baltimore, MD 21209 Attention: Asher M. Rubin; Adriana V. Tibbitts Email: [***]

20.6 Independent Contractors. Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give either Party the power or authority to act

for, bind, or commit the other Party in any way. Nothing herein will be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

20.7 Maintenance of Records. Each Party will maintain complete and accurate records of all work conducted under this Agreement and all results, data and developments made pursuant to its efforts under this Agreement. Such records will be complete and accurate and will fully and properly reflect all work done and results achieved in the performance of this Agreement in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Each Party will keep and maintain all records required by Applicable Law with respect to the Collaboration Compounds and the corresponding Licensed Compounds and Licensed Products.

20.8 No Third Party Beneficiaries. Except as expressly set forth in Article 18, there are no express or implied Third Party beneficiaries hereunder. The provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity will have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.

20.9 Assignment.

(a) Neither Party may assign this Agreement or assign or transfer any rights or obligations hereunder without the prior written consent of the other, which consent will not be unreasonable withheld, conditioned or delayed, except that a Party may make such an assignment or transfer without the other Party's consent (i) to any Affiliate of such Party, or (ii) to any Third Party in connection with the sale of all or substantially all of the business or assets of such Party to which this Agreement relates [***], whether in a merger, combination, reorganization, sale of stock, sale of assets or other transaction; provided, however, that in each case (i) and (ii) that the assigning Party provides written notice to the other Party of such assignment and the assignee will have agreed in writing to be bound (or is otherwise required by operation of Applicable Law to be bound) in the same manner as such assigning Party hereunder. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 20.9 will be null, void and of no legal effect. For clarity, the provisions of this Section 20.9 will not apply to or encompass sublicensing of the rights licensed to a Party under this Agreement. Subject to the terms of this Agreement and without limiting Section 2.9 or 10.5, each Party and its Affiliates and, in the case of Blueprint, its Sublicensees, will have the right to enter into subcontracts in connection with the exercise of its rights and the performance of its obligations under this Agreement and this Section 20.9 will not apply with respect thereto. [***].

(b) **Effect of Change of Control**. In the event that either Party undergoes a Change of Control with a Third Party (an Acquirer as defined below), then:

(i) the Material, Information, Patents or intellectual property of such Acquirer owned or controlled by such Acquirer or any of such Acquirer's Affiliates prior to such acquisition ("**Acquirer Technology**") will not be deemed "Controlled" by such Party or its Affiliates and will be excluded from, and will not be used or incorporated into, the Proteovant Technology, Blueprint Technology, or Product Patents (as applicable); and

(ii) any Intellectual Property Right that, following such Change of Control, is (A) created, conceived, developed, made or otherwise acquired or controlled by the Acquirer or any of such Acquirer's Affiliates (other than the Acquired Party) (x) without use of Proteovant Know-How, Proteovant [***] Know-How, Blueprint Know-How, Blueprint Target Binder Compound Know-How, the Proteovant Confidential Information, the Joint Confidential Information or Blueprint's Confidential Information (including any data, results, Blueprint Target Binder Compounds, Materials or other Information from, or that is, was, or will be used in conducting, the Target Program) (collectively, the "**Subject Information**"), and (y) without the use of the Acquired Party's personnel working on or performing, or who have worked on or performed, the Target Program (collectively, "**Subject Personnel**") and (B) has been held subject to firewalls established to prevent access and sharing between Subject Personnel and Acquirer's and its Affiliates' personnel working on such other intellectual property (such intellectual property that satisfies all of the foregoing clauses, the "**Segregated Technology**") will not be deemed "Controlled" by the Acquired Party or its Affiliates and will be excluded from, and will not be used or incorporated into, the Proteovant Technology, Blueprint Technology, or Product Patents (as applicable).

(iii) as used herein, "**Acquirer**" means the Third Party involved in the Change of Control, and any Affiliate of such Third Party that was not an Affiliate of the Acquired Party immediately prior to the effective date of the Change of Control, and but, for clarity, does not include any successors to an Acquired Party; and "**Acquired Party**" means the Party that was the subject of such Change of Control, together with any entity that was its Affiliate immediately prior to the effective date of the Change of Control, and any of their successors.

20.10 Governing Law. This Agreement will be governed by and construed and enforced under the substantive laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise make this Agreement subject to the substantive law of another jurisdiction. For clarification, any dispute relating to the inventorship, scope, validity, enforceability or infringement of any patent right will be governed by and construed and enforced in accordance with the patent laws of the applicable jurisdiction.

20.11 Performance by Affiliates. Subject to the terms and conditions of this Agreement, each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

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

20.13 Compliance with Applicable Law. Each Party will comply with Applicable Law in the course of performing its obligations or exercising its rights pursuant to this Agreement. Notwithstanding anything to the contrary in this Agreement, neither Party nor any of its Affiliates

will be required to take, or will be penalized for not taking, any action that such Person reasonably believes is not in compliance with Applicable Law.

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

20.15 No Waiver. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances will be construed as a continuing waiver of such condition or term or of another condition or term.

20.16 Interpretation. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits of this Agreement and references to this Agreement include all Exhibits hereto. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words “include”, “includes” or “including” will be construed as incorporating also the phrase “but not limited to” or “without limitation”; (b) the word “day” will mean calendar day (unless Business Day is specified); (c) the word “notice” will mean notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits); (e) provisions that require that a Party, the Parties, the JRC or the JSC hereunder “agree,” “consent” or “approve” or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (f) words of any gender include the other gender; (g) words using the singular or plural number also include the plural or singular number, respectively; (h) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof; (i) the word “will” will be construed to have the same meaning and effect as the word “shall”; and (j) except where the context dictates otherwise “or” has the inclusive meaning represented by the phrase “and/or”. Ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The language of this Agreement will be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto. This Agreement should be interpreted in its entirety and the fact that certain provisions of this Agreement may be cross-referenced in a Section will not be deemed or construed to limit the application of other provisions of this Agreement to such Section and vice versa.

20.17 Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document, each of which will be deemed an original, will be construed together and will constitute one and the same instrument. This Agreement may

be executed and delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[signature page follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives effective as of the Effective Date.

BLUEPRINT MEDICINES CORPORATION	**ONCOPIA THERAPEUTICS, INC.**
By: /s/ Jeff Albers	By: /s/ Andrew Fromkin
Name: Jeffrey Albers	Name: Andrew Fromkin
Title: Chief Executive Officer	Title: Chief Executive Officer

Schedule 1

1. "**Commercial Cost Report**" has the meaning set forth in Section 11.8(c)(i).

2. "**Cost Reports**" has the meaning set forth in Section 11.8(c)(i).

3. "**Development Cost Report**" has the meaning set forth in Section 11.8(c)(i).

4. "**Finance Officers**" has the meaning set forth in Section 11.8(c)(i).

5. "**FTE**" means the equivalent of the work of one (1) person full time for one (1) Calendar Year (consisting of at least a total of [***] hours per Calendar Year). In no event may the same person to be deemed to have worked more than [***] hours in any one Calendar Year or [***] hours in any one calendar month.

6. "**FTE Costs**" means an amount equal to the product of the FTE Rate and actual number of FTEs who performed the applicable [***] activities. For clarity, FTEs will be pro-rated on a daily basis if necessary.

7. "**FTE Rate**" means the cost, mutually agreed by the Parties reasonably and [***] and set forth in the applicable Opt-In Global Development Budget and Operational Budget (which FTE rate will the same for such budgets), per FTE per year, which cost will be commensurate with usual and customary rates in comparable profit share agreements and which will include all direct and indirect costs of a Party's FTE, including personnel and travel. Notwithstanding the foregoing, for any Calendar Year during the Term that is less than a full year, the above referenced rate will be proportionately reduced to reflect such portion of such full Calendar Year.

8. "**Fully-Burdened Manufacturing Costs**" means, with respect to an Opt-In Compound or Opt-In Product, the [***].

9. "**Manufacturing Costs**" has the meaning set forth in **Appendix 1**.

10. "**Medical Affairs**" means, with respect to a Collaboration Compound and the corresponding Licensed Compounds and Licensed Products, the performance of medical or scientific activities by or on behalf of a Party, including but not limited to, development and publication of manuscripts, exhibiting and presenting at medical and scientific seminars and conventions, conducting health economic studies, conducting appropriate activities involving opinion leaders, engaging medical science liaisons and conducting medical science liaison activities, responding to unsolicited requests for information about a product, conveying disease education to health care professionals and consumers, conducting medical advisory board meetings or other consultant programs, and establishing patient registries.

11. "**Operating Budget**" means, with respect to an Opt-In Target Program, the budget for Shared Commercialization Costs included in the Opt-In Commercialization Plan for such Opt-In Target Program.

12. "**Operating Profits or Losses in the Opt-In Territory**" means, for any given time period with respect to a given Opt-In Product, Net Sales of such Opt-In Product in the Opt-In Territory during such time period less the sum of the Shared Commercialization Costs and Fully-Burdened Manufacturing Costs directly relating to the sale of such Opt-In Product in the Opt-In Territory in such time period. Operating Profits or Losses in the Opt-In Territory in any given time period will be determined on an accrual basis from the Parties' books and records maintained in accordance with Accounting Standards.

13. "**Overhead Costs**" means costs incurred by a Party or for its account that are attributable to a Party's supervisory or support services or functions, occupancy costs, corporate bonus (to the extent not charged directly to department), and its payroll, information systems, human relations or purchasing functions and that are allocated to company departments based on space occupied or headcount or other activity-based method, including any such costs attributed to a Party's FTEs or contract personnel or to general corporate activities including, by way of example, executive management, investor relations, business development, legal affairs, and finance.

14. "**Permitted U.S. Budget Overrun**" has the meaning set forth in Section 11.8(a)(i).

15. "**Product Liability Costs**" means, all Out-of-Pocket Costs (including reasonable attorneys', costs of litigation, including experts' fees) and expenses paid to Third Parties), damages paid to Third Parties and other amounts paid in settlement to Third Parties, other than those claims or actions for which a Party is entitled to indemnification under Section 18.1 (a)-(b) (with respect to Blueprint Claims), or Section 18.2 (b)-(c) (with respect to Proteovant Claims). For clarity, "**Product Liability Costs**" will be net of any amounts covered and paid by insurance for such product liability claims, and Blueprint agrees to use commercially reasonable efforts to cause its respective insurers to pay, or cause any Third Party's insurer to pay, all Product Liability Costs covered under such party's respective insurance.

16. "**Sales and Marketing Expenses**" means the sum of (a) FTE Costs and (b) Out-of-Pocket Costs that are incurred as an expense in accordance with Accounting Standards (excluding Third Party Payments) other than those deducted as part of the calculation of Net Sales, in each case that are directly allocable to the Parties' Co-Commercialization of an Opt-In Product in the Opt-In Territory and consistent with the Opt-In Commercialization Plan for such Opt-In Product, whether before or after the First Commercial Sale of such Opt-In Product in the Opt-In Territory; provided that Sales and Marketing Expenses will specifically exclude the cost of activities that promote any of the following: (i) a Party's business as a whole without being Opt-In Product-specific (such as corporate image advertising) or (ii) any other products of either Party that are not the Opt-In Product.

17. "**Shared Commercialization Costs**" means, with respect to an Opt-In Product, the sum of the following: (a) all FTE Costs and Out-of-Pocket Costs, (b) Sales and Marketing Expenses, (c) any Third Party Payments paid by either Party under a Third Party Agreement, (d) Out-of-Pocket Costs that are incurred as an expense in accordance with Accounting Standards (excluding Third Party Payments), and (e) Product Liability Costs, in each case ((a)-(e)), incurred by or on behalf of a Party or its Affiliates commencing on

the date Blueprint exercises its Option with respect to the applicable Collaboration Compound and continuing thereafter during the appliable Opt-In Term, to the extent attributable to the Commercialization of such Opt-In Product in the Opt-In Territory and any Medical Affairs activities in support of such Commercialization, consistent with the Opt-In Commercialization Plan and the Operating Budget for such Opt-In Product, including Overhead Costs attributable to the Commercialization of such Opt-In Product in the Opt-In Territory. No Shared Development Cost will be a Shared Commercialization Cost under this Agreement and no expense deducted from Net Sales will also be a Shared Commercialization Cost. Shared Commercialization Costs specifically exclude (i) any costs or expenses of a Party or any of its Affiliates to the extent caused by such Party or any of its Affiliate's breach of this Agreement, and (ii) any costs or expenses of a Party or any of its Affiliates that are incurred solely for the purposes of Commercializing a Licensed Product outside of the Opt-In Territory.

18. "**Shared Costs**" means any Shared Commercialization Costs or Shared Development Costs.

19. "**Shared Development Costs**" means, with respect to an Opt-In Product, the sum of the following: (a) all FTE Costs and all Out-of-Pocket Costs, (b) any Third Party Payments paid by either Party under a Third Party Agreement, (c) the Fully-Burdened Manufacturing Cost for the quantities of Opt-In Compound and Opt-In Product used, and (d) Product Liability Costs, in each case ((a)-(d)), incurred by or on behalf of a Party or its Affiliates commencing on the date Blueprint exercises its Option with respect to the applicable Collaboration Compound and continuing thereafter during the appliable Opt-In Term, to the extent attributable to the Development (but for clarity, not including any Research activities under a Research Plan) of such Opt-In Product in the Territory and any Medical Affairs, regulatory or pharmacovigilance activities in support of such Development activities for such Opt-In Product in the Territory, consistent with the Opt-In Global Development Plan and the Opt-In Global Development Budget for such Opt-In Product, including the performance of any Nonclinical Studies and Clinical Trials and development of any CDx for use with such Opt-In Product, in all cases, that are recorded as an expense in accordance with Accounting Standards. For clarity, Shared Development Costs will include Overhead Costs attributable to the Development of such Opt-In Product in the Territory to the extent that such Overhead Costs are necessary to enable Development activities that generate Shared Development Costs. No Shared Commercialization Cost will be a Shared Development Cost under this Agreement. Shared Development Costs specifically exclude (i) capital expenditures, (ii) any costs or expenses of a Party or any of its Affiliates to the extent caused by such Party or any of its Affiliate's breach of this Agreement, (iii) any cost or expenses of [***]), (iv) any costs or expenses of Development activities in a country or region where Blueprint has granted a Third Party a sublicense of its rights under Section 10.1(b), provided such Third Party (and not Blueprint) will be responsible for such costs and expenses, and (v) all costs incurred by a Party prior to Blueprint exercising its Option with respect to the applicable Opt-In Product.

"**Manufacturing Cost**" means the fully burdened cost of Manufacturing Licensed Products (or other component(s) contained therein or placebo, as applicable), including any devices and other delivery technologies that are packaged or otherwise distributed with such Licensed Product, to be used in the calculation of Fully-Burdened Manufacturing Costs, which equals the sum of (a) Direct Costs and Indirect Costs (each as defined below) incurred by a Party, (b) the amounts paid by a Party to a Third Party contract manufacturer as invoiced to such Party, including any fees paid to such Third Party as prepayments or to reserve capacity for the Licensed Products and any cancellation or early termination fees (provided that the Party incurring any cancellation or early termination fees used commercially reasonable efforts to mitigate such fees), and any value-added tax or similar tax due for amounts paid to such Third Party directly attributable to such Licensed Product, and any capital expenditures to the extent incurred for the Licensed Product, and (c) direct distribution expense (including without limitation, freight, postage, shipping, customs, duties and insurance charges) incurred for such Licensed Products, except to the extent such expenses were included in calculating Net Sales, in each case, (i) without any mark-up; provided that the Parties will share depreciation of any internal capital expenditures, if any, to the extent incurred for the Licensed Product, and (ii) but including any Direct Costs or Indirect Costs incurred by a Party to supervise and coordinate the foregoing activities performed by a Third Party. Manufacturing Cost will include costs incurred with respect to, or as a result of, spoilage, obsolescence, failed or destroyed batches of Licensed Product except to the extent attributable to a Party's or any of its Affiliates' negligence or willful misconduct. Notwithstanding anything to the contrary contained herein, Manufacturing Costs will exclude any and all costs incurred in connection with establishing, or otherwise causing to become operational, any Manufacturing facilities, including any validation, technology transfer (other than the Manufacturing technology transfer costs) and licensure costs, and such costs will be borne solely by the Party who is establishing or operationalizing (itself or through its Affiliate or Third Party contract manufacturer) such Manufacturing facilities.

For purposes of this Appendix 1, "**Direct Costs**" equals the sum of the following as incurred for Licensed Products:

(a) Direct labor, based on the actual hours or like methodology consumed by manufacturing, facility, and customer service personnel for Licensed Products charged at an average hourly wage rate that is designed to approximate actual cost for each employee's position.

(b) Direct labor fringe benefits, including, compensation expense (other than wages included in direct labor cost in clause (a)), payroll taxes and benefits allocated based on a proportionate percentage of direct labor costs charged to the Licensed Products to total actual plant-wide labor costs, plus Licensed Product-specific travel.

(c) Materials and supplies for making Licensed Products, based on actual costs including any applicable freight, taxes, duties, customs or import fees, less any discounts or free goods.

(d) Other costs directly associated with or actually consumed for Licensed Products, including handling, storage, distribution, and transportation costs, facility costs, depreciation, waste removal, miscellaneous supplies, outside testing, consulting fees, occupancy costs, maintenance, rent,

insurance, site service support, warehouse, customer services including order entry, billing and adjustments, inquiry and credit and collection, serialization, return and recall management, but for clarity, excluding in each case any such amounts to the extent included as a deduction in calculating Net Sales, as applicable.

For purposes of this Appendix 1, "**Indirect Costs**" equals the sum of the following as incurred for Licensed Products:

(i) Plant support services, which includes quality control, process sciences, quality assurance, regulatory and validation. All general costs for each plant support service department, which includes, labor, payroll taxes, fringe benefits, materials and supplies, outside testing, consulting fees, contractor costs, depreciation, maintenance and occupancy costs, will be allocated to the cost of Licensed Products based on the proportion of actual labor hours consumed by each plant support service department on the Licensed Products to total actual labor hours consumed by each plant support service department on all of the applicable Party's products.

(ii) Overhead costs required to support the Manufacture of the Licensed Products. These overhead costs are allocated either based on actual labor hours, average headcount, space occupied, or other activity-based method, solely to the extent such allocation is attributable to Licensed Products and not to other products. Overhead costs primarily include general materials and supplies, consulting costs, and other labor costs such as general plant maintenance, management, engineering, janitorial services and administration, information services, human relations, travel and training, and vacation, holiday, personal and sick time, general facility costs which include facility services and supplies, utilities, rent, real estate taxes, depreciation, general and preventative maintenance, insurance and waste removal.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

TENTH AMENDMENT TO COLLABORATION AND LICENSE AGREEMENT

This Tenth Amendment (this "**Tenth Amendment**"), effective April 30 2022 ("**Tenth Amendment Effective Date**"), is by and between F. Hoffmann-La Roche Ltd, with an office and place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland and Hoffmann-La Roche Inc., with an office and place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424 U.S.A. (together referred to as "**Roche**"), and Blueprint Medicines Corporation, with a principal place of business at 45 Sidney Street, Cambridge, Massachusetts 02139 U.S.A. ("**BPM**"). Capitalized terms used and not otherwise defined in this Tenth Amendment shall have the meanings set forth in the Agreement (as defined below).

WHEREAS, BPM and Roche entered into a Collaboration and License Agreement, dated March 14, 2016, as amended by an amendment, effective April 15, 2016, a second amendment, effective April 27, 2016, a third amendment, effective August 4, 2016, a fourth amendment, effective February 25, 2019, a fifth amendment, effective June 28, 2019, a sixth amendment effective November 1, 2019, a seventh amendment effective December 17, 2019, an eighth amendment effective April 30, 2020, and a ninth amendment effective January 8, 2021 (collectively, the "**Agreement**");

WHEREAS, BPM and Roche desire to amend certain terms under the Agreement related to [***] and the FTE Rate (as defined below), as set forth below;

NOW THEREFORE, Roche and BPM hereby agree as follows:

1. Section 1.86 (Option Period) of the Agreement shall be deleted in its entirety and replaced by the following:

"The term 'Option Period' shall mean, for each Collaboration Target, the period beginning on the date the MTD for the first Product for such Collaboration Target is designated by the JDC and ending upon the earliest of (i) the date that such Collaboration Target becomes a Leftover Target, (ii) [***] after Roche's receipt of the Option Data Package for such Collaboration Target, (iii) the date such Collaboration Target becomes a Terminated Target, (iv) the date upon which a Product (including Backup Compounds) for such Collaboration Target is no longer in GLP Tox Studies, in Phase I Studies, or progressing from GLP Tox Studies to Phase I Studies, or (v) [***] after achievement of Lead Series Identified Criteria has been confirmed by the JRC for such Collaboration Target if Initiation of the GLP Tox Study has not been achieved for such Collaboration Target prior to such date; *provided, however*, that

(a) [***] for purposes of this clause 1.86(v), [***]. In the event that the JRC subsequently [***]; and

(b) [***] for purposes of this clause 1.86(v), [***].

2. In the event that (A) Initiation of the GLP Tox Study [***], (B) prior to [***] the JRC determines [***], or (C) prior to [***] the JRC determines [***] shall not be continued for any other reason, then [***] shall automatically be classified as a "Terminated Target" under the Agreement in all countries in the Territory as if terminated in accordance with Section 21.2.4 (the failure to satisfy the deadline under clause (A) or the occurrence of the trigger under clause (B), as applicable, is hereinafter referred to as the [***]). Notwithstanding the written notice period set forth in such Section 21.2.4, the effective date of termination of such Terminated Target will be the [***]. Further, effective as of the [***] this Tenth Amendment will be deemed to constitute a "Continuation Election Notice" in accordance with Section 21.3.1 and Roche will comply with its obligations under 21.3.1 and 21.3.4; *provided* that no payment will be due or payable to Roche under Section 21.3.1(f) or 21.3.4.4. As of the [***], (a) the rights and licenses granted by BPM to Roche under the Agreement related to [***] will terminate in their entirety in all countries in the Territory, (b) except as set forth herein, the rights and obligations of the Parties under the Agreement will terminate with respect to [***], (c) Roche's obligations under Section 20.1 will survive with respect to [***], (d) BPM will solely own all Collaboration Compounds and Other Compounds for [***], including their methods of manufacture and use, and all Patent Rights and Know-How relating thereto, and (e) BPM will have the right to (i) research, develop, manufacture, commercialize and otherwise exploit compounds and products related to [***] outside of the Agreement without any financial obligations to Roche, (ii) publish data and other Know-How related to [***] (including without limitation Collaboration Compounds and Other Compounds for such Terminated Target) generated by or on behalf of the Parties under the Agreement prior to the [***] or thereafter without obtaining prior review or approval from Roche and (iii) disclose, in its sole discretion, in a manner consistent with BPM's then-current disclosure or publication practices or policies, that such data or Know-How was generated under the Agreement and/or the names and affiliations of the individuals involved in the generation of such data or Know-How, if and as applicable.

3. Consistent with JRC discussions [***], notwithstanding anything to the contrary in the Agreement, (a) [***], (b) the [***] listed on Schedule A [***], and (c) [***].

4. Effective [***], with respect to a Party for any period, personnel costs referenced under Sections 1.39 (Development Costs) and 1.96 (Phase I Development Costs) of the Agreement means the applicable FTE Rate (as defined below) multiplied by the applicable number of FTEs (as defined below) of such Party performing activities during such period in accordance with the applicable Phase I Plan (including applicable Phase I Development Costs) and Development Plan (including Development Costs).

> "**FTE**" means the equivalent of a full-time individual's work time for a twelve (12) month period, where "full-time" is determined by [***] hours per year. In the event that any individual who works full-time during a given fiscal year works partially on Collaboration Compounds, Products, Licensed Products or Companion Diagnostics for such Collaboration Targets or in furtherance of the Collaboration and partially on other work outside the Collaboration in the fiscal year, then the full-time equivalent to be attributed to such individual's work hereunder for such fiscal year shall be equal to the percentage of such individual's total work time in such fiscal year that such individual spent working on Collaboration Compounds, Products, Licensed Products or Companion Diagnostics for such Collaboration Targets or in furtherance of the Collaboration. FTE efforts shall not include the work of alliance management, executive management and general corporate or administrative personnel.

"**FTE Rate**" means [***] per one (1) full FTE per full twelve (12) month Calendar Year; *provided*, that, starting [***], such rate [***]. Notwithstanding the foregoing, for any Calendar Year during the Term that is less than a full year, the above referenced rate shall be proportionately reduced to reflect such portion of such full Calendar Year.

5. This Tenth Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or other electronic signature) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

6. This Tenth Amendment shall be effective as of the Tenth Amendment Effective Date. On and after the Tenth Amendment Effective Date, each reference in the Agreement to "this Agreement," "hereunder," "hereof," "herein" or words of like import, and each similar reference in the other documents entered into in connection with the Agreement, shall mean and be a reference to the Agreement, as amended by this Tenth Amendment. Except as specifically amended above, the Agreement shall remain in full force and effect in accordance with its terms and is hereby ratified and confirmed.

7. This Tenth Amendment shall be governed by and construed in accordance with the laws of the State of New York, without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention).

[Signature page follows]

IN WITNESS WHEREOF, the Parties have caused this Tenth Amendment to be executed by their respective duly authorized representatives as of the Tenth Amendment Effective Date.

Blueprint Medicines Corporation

/s/ Kathryn Haviland

Name: Kathryn Haviland

Title: President & Chief Executive Officer

F. Hoffmann-La Roche Ltd

/s/ Markus Keller

Name: Markus Keller

Title: Global Alliance & Asset Management Director

/s/ Stefan Arnold

Name: Stefan Arnold

Title: Head Legal Pharma

Hoffmann-La Roche Inc.

/s/ John P. Parise

Name: John P. Parise

Title: Authorized Signatory

[***]

[***]

Exhibit 31.1

CERTIFICATIONS

I, Kathryn Haviland, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Blueprint Medicines Corporation;

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.

Date: May 3, 2022

By:/s/ Kathryn Haviland
Kathryn Haviland
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Michael Landsittel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Blueprint Medicines Corporation;

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.

Date: May 3, 2022

By: /s/ Michael Landsittel
Michael Landsittel
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Blueprint Medicines Corporation (the "Company") for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 3, 2022

By: /s/ Kathryn Haviland
Kathryn Haviland
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 3, 2022

By: /s/ Michael Landsittel
Michael Landsittel
Chief Financial Officer
(Principal Financial Officer)