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 September 30, 2022

OR

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

For the transition period from to

Commission File Number: 001-39787

BIOATLA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-1922320**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11085 Torreyana Road, San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 558-0708

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, $0.0001 par value per share	BCAB	The Nasdaq Global Market

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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

As of November 2, 2022, the number of shares of the registrant's common stock outstanding was 36,395,338 and the number of shares of the registrant's Class B common stock outstanding was 1,211,959.

BIOATLA, INC.
Quarterly Report on Form 10-Q

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

BioAtla, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except par value and share amounts)

	September 30, 2022 (unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 178,120	$ 244,979
Prepaid expenses and other current assets	5,189	2,313
Total current assets	183,309	247,292
Property and equipment, net	3,002	3,676
Operating lease right-of-use asset, net	2,647	3,300
Other assets	154	154
Total assets	$ 189,112	$ 254,422
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 22,327	$ 18,424
Operating lease liabilities	1,498	1,389
Total current liabilities	23,825	19,813
Operating lease liabilities, less current portion	2,847	3,982
Liability to licensor	19,806	19,806
Total liabilities	46,478	43,601
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 0 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized at September 30, 2022 and December 31, 2021; 36,365,317 and 35,799,233 shares issued and outstanding at September 30, 2022 and December 31, 2021	4	4
Class B common stock, $0.0001 par value; 15,368,569 shares authorized at September 30, 2022 and December 31, 2021; 1,211,959 and 1,492,059 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	407,888	397,136
Accumulated deficit	(265,258)	(186,319)
Total stockholders' equity	142,634	210,821
Total liabilities and stockholders' equity	$ 189,112	$ 254,422

See accompanying notes.

BioAtla, Inc.
Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration and other revenue	$ —	$ —	$ —	$ 250
Operating expenses:				
Research and development expense	19,839	16,553	57,473	41,826
General and administrative expense	6,340	7,142	22,107	31,376
Total operating expenses	26,179	23,695	79,580	73,202
Loss from operations	(26,179)	(23,695)	(79,580)	(72,952)
Other income (expense):				
Interest income	370	76	601	254
Interest expense	—	—	—	(3)
Gain on extinguishment of long-term debt	—	690	—	690
Other income (expense)	30	(1)	40	(1)
Total other income (expense)	400	765	641	940
Consolidated net loss and comprehensive loss	$ (25,779)	$ (22,930)	$ (78,939)	$ (72,012)
Net loss per common share, basic and diluted	$ (0.69)	$ (0.68)	$ (2.11)	$ (2.13)
Weighted-average shares of common stock outstanding, basic and diluted	37,516,769	33,909,460	37,420,531	33,751,558

See accompanying notes.

BioAtla, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Three Months Ended September 30, 2022						
	Common Stock		Class B Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at June 30, 2022	35,993,458	$ 4	1,492,059	$ —	$ 404,427	$ (239,479)	$ 164,952
Stock-based compensation expense	—	—	—	—	3,588	—	3,588
Issuance of common stock under equity incentive plans, net of shares withheld for taxes	91,759	—	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	—	—	—	—	—	—	—
Taxes related to net share settlement of equity awards	—	—	—	—	(127)	—	(127)
Conversion of Class B common stock	280,100	—	(280,100)	—	—	—	—
Net loss	—	—	—	—	—	(25,779)	(25,779)
Balance at September 30, 2022	36,365,317	$ 4	1,211,959	$ —	$ 407,888	$ (265,258)	$ 142,634

	Three Months Ended September 30, 2021						
	Common Stock		Class B Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at June 30, 2021	32,315,301	$ 3	1,492,059	$ —	$ 318,019	$ (139,999)	$ 178,023
Stock-based compensation expense	—	—	—	—	4,366	—	4,366
Issuance of common stock, net of issuance costs	2,678,600	1	—	—	71,053	—	71,054
Issuance of common stock under equity incentive plans	188,780	—	—	—	—	—	—
Issuance of common stock upon exercise of options, net	7,747	—	—	—	140	—	140
Issuance of common stock for Employee Stock Purchase Plan	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	(22,930)	(22,930)
Balance at September 30, 2021	35,190,428	$ 4	1,492,059	$ —	$ 393,578	$ (162,929)	$ 230,653

See accompanying notes.

BioAtla, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Nine Months Ended September 30, 2022						
	Common Stock		Class B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	35,799,233	$ 4	1,492,059	$ —	$ 397,136	$ (186,319)	$ 210,821
Stock-based compensation expense	—	—	—	—	11,062	—	11,062
Issuance of common stock under equity incentive plans, net of shares withheld for taxes	276,502	—	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	9,482	—	—	—	19	—	19
Taxes related to net share settlement of equity awards	—	—	—	—	(329)	—	(329)
Conversion of Class B common stock	280,100	—	(280,100)	—	—	—	—
Net loss	—	—	—	—	—	(78,939)	(78,939)
Balance at September 30, 2022	36,365,317	$ 4	1,211,959	$ —	$ 407,888	$ (265,258)	$ 142,634

	Nine Months Ended September 30, 2021						
	Common Stock		Class B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	32,171,560	$ 3	1,492,059	$ —	$ 300,888	$ (90,917)	$ 209,974
Stock-based compensation expense	—	—	—	—	21,307	—	21,307
Issuance of common stock, net of issuance costs	2,678,600	1	—	—	71,053	—	71,054
Issuance of common stock under equity incentive plans	327,241	—	—	—	—	—	—
Issuance of common stock upon exercise of options, net	7,747	—	—	—	140	—	140
Issuance of common stock for Employee Stock Purchase Plan	5,280	—	—	—	190	—	190
Net loss	—	—	—	—	—	(72,012)	(72,012)
Balance at September 30, 2021	35,190,428	$ 4	1,492,059	$ —	$ 393,578	$ (162,929)	$ 230,653

See accompanying notes.

BioAtla, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (78,939)	$ (72,012)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	901	1,016
Loss on disposal of property and equipment	6	4
Gain on extinguishment of debt	—	(690)
Stock-based compensation	11,062	21,307
Accrued interest	—	3
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,876)	(1,516)
Accounts payable and accrued expenses	4,146	10,844
Right-of-use assets and lease liabilities, net	(373)	(221)
Net cash used in operating activities	(66,073)	(41,265)
Cash flows from investing activities		
Purchases of property and equipment	(237)	(835)
Proceeds from sale of property and equipment	3	—
Net cash used in investing activities	(234)	(835)
Cash flows from financing activities		
Payment of initial public offering costs	—	(1,911)
Proceeds from issuance of common stock	—	75,001
Proceeds from exercise of stock options	—	140
Proceeds from issuance of common stock under Employee Stock Purchase Plan	19	190
Payments for taxes related to net settlement of equity awards	(571)	—
Net cash provided by (used in) financing activities	(552)	73,420
Net increase (decrease) in cash and cash equivalents	(66,859)	31,320
Cash and cash equivalents, beginning of period	244,979	238,605
Cash and cash equivalents, end of period	$ 178,120	$ 269,925
Supplemental disclosure of non-cash investing and financing activities		
Property and equipment additions included in accounts payable and accrued expenses	$ 1	$ 8
Equity issuance costs included in accounts payable and accrued expenses	$ —	$ 3,947
Tax related to net settlement of equity awards included in accounts payable and accrued expenses	$ 49	$ —

See accompanying notes.

1. Organization and Summary of Significant Accounting Policies

Organization

BioAtla, LLC was formed in Delaware in March 2007 and, after undergoing two separate reorganizations in 2019 and in 2020, was converted to a Delaware corporation in July 2020 and was renamed BioAtla, Inc. (the “Company”). The Company has a proprietary platform for creating biologics, including its conditionally active biologics (“CAB” or “CABs”). CABs have been designed to be active only under certain conditions found in diseased tissue, while remaining inactive in normal tissue. The Company is currently in clinical development of its two lead CAB antibody drug conjugates (“CAB ADC”) targeting AXL and ROR2 receptors, and its CAB immune-oncology antibody targeting CTLA-4.

Basis of Presentation and Principles of Consolidation

Prior to the reorganization in July 2020 (or "Corporate Reorganization"), the consolidated financial statements included the accounts of BioAtla, LLC and those of its majority owned subsidiary Himalaya Therapeutics SEZC that had no material operations. Himalaya Therapeutics SEZC also had a wholly owned subsidiary, Himalaya Therapeutics HK Limited that had no material operations. All intercompany balances were eliminated in consolidation. In connection with the Corporate Reorganization, Himalaya Therapeutics SEZC and Himalaya Therapeutics HK Limited were deconsolidated without material impact to the consolidated financial statements. Subsequent to the Corporate Reorganization, BioAtla, Inc. became a single legal entity with no consolidated variable interest entities ("VIEs") or subsidiaries.

The unaudited condensed consolidated financial statements as of September 30, 2022, and for the three and nine months ended September 30, 2022 and 2021, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”), and with accounting principles generally accepted in the United States (“GAAP”) applicable to interim financial statements. These unaudited condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company’s financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year or future periods. These unaudited condensed consolidated financial statements should be read in conjunction with the Company’s audited financial statements for the year ended December 31, 2021, included in its Annual Report on Form 10-K filed with the SEC on February 28, 2022.

Liquidity and Going Concern

The Company has incurred cumulative operating losses and negative cash flows from operations since its inception and expects to continue to incur significant expenses and operating losses for the foreseeable future as it continues the development of its product candidates. As of September 30, 2022, the Company had an accumulated deficit of $265.3 million. The Company plans to continue to fund its losses from operations and capital funding needs through public or private equity or debt financings or other sources. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company’s business, results of operations and future prospects.

Management is required to perform a two-step analysis of the Company’s ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern (Step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (Step 2). Management’s assessment included the preparation of cash flow forecasts resulting in management’s conclusion that there is not substantial doubt about the Company’s ability to continue as a going concern as its current cash and cash equivalents will be sufficient to fund the Company’s operations for a period of at least one year from the issuance date of these unaudited condensed consolidated financial statements.

Use of Estimates

The preparation of the Company’s condensed consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company’s condensed consolidated financial statements and accompanying notes. The most significant estimates in the Company’s condensed consolidated financial statements relate to revenue recognition, accruals for research and development costs, and equity-based compensation. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenue and expenses that are not readily apparent from other sources. Actual

results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Concentrations of Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of equity awards, consisting of stock options, restricted stock units ("RSUs") and employee stock purchase plan rights, over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The Company estimates the fair value of stock option grants and employee stock purchase plan rights using the Black-Scholes option pricing model. Prior to the Company's IPO, the fair value of RSUs was based on the estimated fair value of the underlying common stock on the date of grant and, subsequent to the Company's IPO, the fair value is based on the closing sales price of the Company's common stock on the date of grant. Equity award forfeitures are recognized as they occur.

Leases

The Company determines if an arrangement is a lease at inception. An arrangement is or contains a lease if it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. If a lease is identified, classification is determined at lease commencement. Operating lease liabilities are recognized at the present value of the future lease payments at the lease commencement date. The Company's leases do not provide an implicit interest rate and therefore the Company estimates its incremental borrowing rate to discount lease payments. The incremental borrowing rate reflects the interest rate that the Company would have to pay to borrow on a collateralized basis an amount equal to the lease payments in a similar economic environment over a similar term. Operating lease right-of-use ("ROU") assets are based on the corresponding lease liability adjusted for any lease payments made at or before commencement, initial direct costs, and lease incentives. Renewals or early terminations are not accounted for unless the Company is reasonably certain to exercise these options. Operating lease expense is recognized and the ROU asset is amortized on a straight-line basis over the lease term. Variable lease costs are not included in the calculation of the ROU asset and the related lease liability and are recognized as incurred.

The Company has a single lease agreement with lease and non-lease components, which are accounted for as a single lease component. Payments for short-term leases, defined as leases with a term of twelve months or less, are expensed on a straight-line basis over the lease term. The Company does not currently have any short-term leases.

Operating leases are included in operating lease right-of-use assets, operating lease liabilities, and operating lease liabilities, non-current on the Company's consolidated balance sheets. The Company does not have any finance leases.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. There have been no items qualifying as other comprehensive loss and, therefore, for all periods presented, the Company's comprehensive loss was the same as its reported net loss.

Net Loss Per Share

Basic net loss per common share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of RSUs, common stock options outstanding under the Company's stock option plan, and contingently issuable shares under the Company's ESPP plan.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalents):

	Nine Months Ended September 30,	
	2022	2021
Common stock warrants	—	717,674
Common stock options	2,718,930	960,402
Restricted stock units	629,007	1,592,796
ESPP shares	115,783	4,109
Total	3,463,720	3,274,981

Recent Accounting Pronouncements

There were no new accounting standards that had a material impact on the Company's consolidated financial statements during the three or nine months ended September 30, 2022, and there were no other new accounting standards or pronouncements that were issued but not yet effective as of September 30, 2022 that the Company expects to have a material impact on its consolidated financial statements.

2. Balance Sheet Details

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Prepaid research and development	$ 3,978	$ 1,811
Prepaid insurance	692	—
Other prepaid expenses and current assets	519	502
Total	$ 5,189	$ 2,313

Property and equipment consist of the following (in thousands):

	Useful life (years)	September 30, 2022	December 31, 2021
Furniture, fixtures and office equipment	3 - 7	$ 2,192	$ 2,123
Laboratory equipment	5	2,265	2,123
Leasehold improvements	2 - 3	3,687	3,687
		8,144	7,933
Less accumulated depreciation and amortization		(5,142)	(4,257)
Total		$ 3,002	$ 3,676

Accounts payable and accrued expenses consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Accounts payable	$ 3,696	$ 1,179
Accrued compensation	2,979	2,671
Accrued research and development	14,713	13,501
Other accrued expenses	939	1,073
Total	$ 22,327	$ 18,424

3. Fair Value Measurements

The carrying amounts of the Company's current financial assets and current financial liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. As of September 30, 2022 and December 31, 2021, the Company had no financial assets or liabilities measured at fair value on a recurring basis.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction

between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

None of the Company's non-financial assets and liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

4. Debt

The Company did not have any outstanding debt as of September 30, 2022 or December 31, 2021. In April 2020, the Company borrowed $0.7 million under the Paycheck Protection Program ("PPP") under the CARES Act. The loan was subsequently forgiven in July 2021. The $0.7 million balance of the forgiven loan was recognized as other income on the Company's Statement of Operations for the three and nine months ended September 30, 2021. For the three and nine months ended September 30, 2021, the Company recognized interest expense related to its outstanding debt of $0 and $3,000, respectively.

5. Leases

The Company has a single operating lease for its corporate headquarters and laboratory space in San Diego, California. The lease expires in July 2025 and the Company has an option to extend the term of the lease for an additional five years. Additionally, the lease includes certain rent abatement, rent escalations, tenant improvement allowances and additional charges for common area maintenance and other costs.

The components of lease expense included in the Company's condensed consolidated statements of operations include (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating lease expense	$ 261	$ 261	$ 782	$ 782
Variable lease expense	132	128	328	384
Total lease expense, net	$ 393	$ 389	$ 1,110	$ 1,166

Variable lease costs are primarily related to payments made to lessors for common area maintenance, property taxes, insurance, and other operating expenses. The Company did not have any short-term leases or finance leases for the three and nine months ended September 30, 2022 and 2021, respectively.

The weighted average remaining lease term and weighted average discount rate for operating leases were as follows:

	As of September 30,	
	2022	2021
Weighted average remaining lease term (in years)	2.75	3.75
Weighted average discount rate percentage	3.50%	3.50%

Supplemental cash flow information related to leases under which the Company is the lessee was as follows (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cash paid for amounts included in the measurement of operating leases	$ 401	$ 370	$ 1,155	$ 1,003

As of September 30, 2022, future minimum payments under the Company's non-cancelable operating lease under ASC 842 were as follows (in thousands):

	Operating lease
Three months ending December 31, 2022	$ 401
2023	1,636
2024	1,685
2025	845
Thereafter	—
Total future lease payments	4,567
Less: imputed interest	(222)
Total operating lease liabilities	$ 4,345

6. Commitments and Contingencies

From time to time, the Company may be subject to various claims and suits arising in the ordinary course of business. The Company is not currently a party to any legal proceedings the outcome of which the Company believes, if determined adversely to the Company, would individually or in the aggregate have a material adverse effect on the Company's business, operating results or financial condition.

7. Stockholders' Equity

2020 Equity Incentive Plan

The Company may grant awards of common stock under the 2020 Equity Incentive Plan (the "2020 Plan") to the Company's employees, consultants and non-employee directors pursuant to option awards, stock appreciation rights awards, restricted stock awards, restricted stock unit awards, performance stock awards, performance stock unit awards and other stock-based awards. As of September 30, 2022 and December 31, 2021, the total number of common shares authorized for issuance under the 2020 Plan was 7,658,509 and 6,226,540, respectively. On January 1st of each year, commencing with the first January 1st following the effective date of the 2020 Plan, the shares authorized for issuance under the 2020 Plan shall be increased by a number of shares equal to the lesser of 4% of the total number of shares outstanding on the immediately preceding December 31st and such lesser number of shares determined by the Company's board of directors. The maximum term of the options granted under the 2020 Plan is no more than ten years. Awards under the 2020 Plan generally vest at 25% one year from the vesting commencement date and ratably each month thereafter for a period of 36 months, subject to continuous service.

Stock-based compensation expense for the three and nine months ended September 30, 2022 and 2021 has been reported in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 1,427	$ 1,267	$ 4,125	$ 3,376
General and administrative	2,161	3,099	6,937	17,931
Total	$ 3,588	$ 4,366	$ 11,062	$ 21,307

Restricted Stock Units

The following table summarizes RSU activity under the 2020 Plan for the nine months ended September 30, 2022:

	Number of Shares	Weighted - Average Grant Date Fair Value
Outstanding at December 31, 2021	975,046	$ 18.00
Granted	—	$ —
Vested	(335,305)	$ 18.00
Forfeited	(10,734)	$ 18.00
Outstanding at September 30, 2022	629,007	$ 18.00

As of September 30, 2022, total unrecognized stock-based compensation expense for RSUs was $11.3 million, which is expected to be recognized over a remaining weighted-average period of approximately 1.5 years. During the nine months ended September 30, 2021, the Company modified 138,461 RSU's under the Transition Agreement (See Note 9).

Stock Options

The following table summarizes stock option activity under the 2020 Plan for the nine months ended September 30, 2022:

	Number of Options	Weighted - Average Exercise Price Per Share	Weighted -Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at December 31, 2021	1,086,902	$ 26.76	9.22	$ 991,495
Granted	1,667,200	$ 6.29		
Exercised	—	$ —		
Forfeited	(19,708)	$ 26.95		
Expired	(15,464)	$ 39.12		
Balance at September 30, 2022	2,718,930	$ 14.00	9.06	$ 2,733,693
Vested and expected to vest at September 30, 2022	2,718,930	$ 14.00	9.06	$ 2,733,693
Exercisable at September 30, 2022	408,742	$ 26.18	8.34	$ —

As of September 30, 2022, total unrecognized stock-based compensation cost for unvested common stock options was $16.4 million, which is expected to be recognized over a remaining weighted-average period of approximately 3.1 years. The weighted- average grant date fair value of stock options granted during the nine months ended September 30, 2022 was $4.01 per share. The total fair value of options vested during the nine months ended September 30, 2022 was $5.4 million. During the nine months ended September 30, 2021 the Company modified 7,747 stock options under the Transition Agreement (See Note 9).

The assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option grants were as follows:

	Nine Months Ended September 30,	
	2022	2021
Expected volatility	74.8%	74.7%
Risk-free interest rate	2.09%	0.99%
Expected dividend yield	0.0%	0.0%
Expected term	6.04	5.86

Expected volatility. As the Company's common stock does not have a significant trading history, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.

Risk-free interest rate. The Company bases the risk-free interest rate assumption on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present plans to pay cash dividends.

Expected term. For employees, the expected term represents the period of time that options are expected to be outstanding. Because the Company has minimal historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period. For nonemployees, the expected term is generally the contractual term of the option.

Employee Stock Purchase Plan

The BioAtla, Inc. Employee Stock Purchase Plan (the "ESPP") permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. As of September 30, 2022 and December 31, 2021, a total of 1,229,148 shares

and 833,993 shares, respectively, of common stock were authorized for issuance under the ESPP. The number of shares of common stock authorized for issuance will automatically increase on January 1 of each calendar year, from January 1, 2021 through January 1, 2030 by the least of (i) 1.0% of the total number of common shares of our common stock outstanding on December 31 of the preceding calendar year (calculated on a fully diluted basis), (ii) 929,658 common shares or (iii) a number determined by the Company's board of directors that is less than (i) and (ii). In February 2021, employees began to enroll in the ESPP and the Company's first offering period commenced. The Company issued 9,482 common shares under the ESPP during the nine months ended September 30, 2022. Comparatively, the Company issued 5,280 common shares under the ESPP during the nine months ended September 30, 2021. As of September 30, 2022, 1,208,484 shares of common stock remained available for issuance under the ESPP. Stock-based compensation expense related to the ESPP for the three and nine months ended September 30, 2022 and 2021 was immaterial.

Common Stock Warrants

The Company issued warrants in 2016 in connection with certain advisory services. The warrants became exercisable upon our IPO for a period of 365 and 450 days.

Upon adoption of ASU No. 2018-07 on October 1, 2020, the measurement date of the warrants became fixed in accordance with the guidance, and such fair value was nominal since the warrants were deeply out-of-the-money. In December 2021, a total of 566,586 warrants with an exercise period of 365 days after our IPO expired unexercised. The remaining 151,088 warrants with an exercise period of 450 days after the Company's IPO expired unexercised in March 2022. Accordingly, there are no remaining common stock warrants outstanding and exercisable at September 30, 2022.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance are as follows in common equivalent shares:

	September 30, 2022	December 31, 2021
Warrants for the purchase of common stock	—	151,088
Common stock options and restricted stock units issued and outstanding	3,347,937	2,061,948
Awards available for future issuance under the 2020 Plan	3,022,529	3,211,854
Awards available for future issuance under the ESPP	1,208,484	822,811
Total common stock reserved for future issuance	7,578,950	6,247,701

8. Collaboration, License and Option Agreements

BeiGene

In April 2019, the Company entered into a Global Co-Development and Collaboration agreement (the "BeiGene Collaboration") with BeiGene, Ltd. and BeiGene Switzerland GmbH (collectively "BeiGene"), a commercial-stage biopharmaceutical company, for the development, manufacturing and commercialization of the Company's investigational CAB CTLA-4 antibody (BA3071). The Company and BeiGene amended the Global Co-Development and Collaboration agreement in December 2019 and in October 2020 (the "Amended BeiGene Collaboration"). In 2019, the Company received a total of $25.0 million in non-refundable payments from BeiGene.

Under the terms of the Amended BeiGene Collaboration, BeiGene was generally responsible for developing BA3071 and for global regulatory filings and commercialization. Subject to the terms of the Amended BeiGene Collaboration, BeiGene held an exclusive license with the Company to develop and manufacture the BA3071 candidate globally, and BeiGene was responsible for all costs of development, manufacturing and commercialization globally. The Amended BeiGene Collaboration provided that the Company was eligible to receive tiered royalties on sales worldwide, subsequent development and regulatory milestone payments globally and commercial milestones in the BeiGene territory.

On November 18, 2021, the Company entered into Amendment No. 3 to the Amended BeiGene Collaboration ("Amendment No.3"). Under Amendment No. 3, the Amended BeiGene Collaboration was terminated, subject to survival of certain provisions, and the Company regained the rights to know-how and materials under the Amended BeiGene Collaboration and assumed responsibility for the global development and commercialization of BA3071. As consideration for Amendment No.3, the Company agreed to pay BeiGene mid-single digit royalties on sales worldwide and on a limited basis will share in any upfront and milestone payments received through a sublicense of BA3071. As part of Amendment No.3, the Company reclassified its remaining $19.8 million of deferred revenue as a long-term liability which is expected to settle as licensing payments are made to BeiGene in accordance with the resulting amendment. In the event the license is terminated, the liability will be extinguished with no further payment to BeiGene.

For the three and nine months ended September 30, 2022 and 2021, the Company did not recognize any revenue related to the collaboration agreement with BeiGene. As of September 30, 2022 and December 31, 2021, the Company had a $19.8 million Liability to Licensor, and $19.8 million of deferred revenue which was classified as current, respectively.

Service Contracts

Prior to developing its own programs, the Company entered into various fixed price research service contracts. In connection with those service contracts, the Company may receive future milestone payments if certain clinical, regulatory and commercialization milestones are achieved. The Company is also eligible to receive royalties based on certain product sales. The Company recognized revenue of $0.3 million, included in “Collaboration and Other Revenue”, for the nine months ended September 30, 2021 related to the achievement of a clinical milestone on a fixed price service contract. The Company did not recognize any revenue related to its legacy service contracts during the three or nine months ended September 30, 2022.

BMS Collaboration

In January 2022, the Company entered into a Master Clinical Trial Collaboration Agreement (the “BMS Collaboration”) with Bristol-Myers Squibb Company (“BMS”) pursuant to which the Company and BMS will investigate the Company’s CAB-ADC candidates, mecbotamab vedotin (BA3011) and ozuriftamab vedotin (BA3021), each in combination with Opdivo (the “BMS Compound”) in clinical trials (each a “Combined Therapy Study”). Opdivo has received approval for several anti-cancer indications.

Under the BMS Collaboration, the Company will serve as the study sponsor for each Combined Therapy Study and will be responsible for the costs associated with trial execution. BMS will supply the Company with clinical drug supply of the BMS Compound at no cost to the Company for each study as well as provide input on certain clinical and regulatory aspects of each Combined Therapy Study in exchange for jointly owning clinical data. The BMS collaboration may be early terminated if a party is in material breach, if either party files for bankruptcy, or due to the existence of a material safety issue. Subject to earlier termination, the BMS Collaboration shall remain in effect until completion and delivery of final study documents for each of the Combined Therapy Study to both parties.

Himalaya Therapeutics

Exclusive Rights Agreement

On January 1, 2020, the Company entered into an Amended and Restated Exclusive Rights Agreement (the “Amended Rights Agreement”) with Himalaya Therapeutics SEZC. Under the terms of the Amended Rights Agreement, Himalaya Therapeutics SEZC acquired the rights to 10 CAB-antibodies for the territory of China, Macao, Hong Kong and Taiwan with future rights to 2 or more CAB-antibodies, global rights to a CAB-HER2-bispecific-antibody and global co-development rights with us to an IL-22 non-CAB-antibody. Payments to the Company may include upfront payments, milestone payments and double-digit royalties, which represent a variable interest held by the Company, but no payments have been made to the Company to date. Himalaya Therapeutics SEZC is a related party.

9. Related Party Transactions

Carolyn Anderson Short

Transition Agreement

On March 23, 2021, the Company entered into a transition agreement with Ms. Anderson Short, our Co-founder and Executive Vice President and Chief of Intellectual Property and Strategy at that time. Pursuant to this transition agreement, Ms. Anderson Short continued in her role with the same base salary and employee benefits until her employment with the Company was terminated on May 31, 2021. Upon her separation from the Company and subject to her execution of a release of claims, Ms. Anderson Short received the following severance benefits as set forth in the transition agreement, which satisfied existing severance obligations owing to her under a legacy pre-IPO severance agreement she had entered into with the Company on July 1, 2018: (i) a lump sum payment equal to 18 months of Ms. Anderson Short's then-current base salary, (ii) a payment at her targeted bonus rate for 2021, pro-rated to the date of her termination of employment, and (iii) full accelerated vesting of her equity awards including 7,747 stock options and 138,461 restricted stock units. The modification of these equity awards resulted in an incremental fair value of $7.0 million which was recognized on a straight-line basis over the transition service period which ended on the separation date. For the three and nine months ended September 30, 2021, the Company recognized $0 and $1.0 million, respectively, related to the lump sum salary payment and target bonus. The Company also recognized non-cash stock-based compensation charges of $0 and $9.4 million related to the modified equity awards for the three and nine months ended September 30, 2021, respectively. No unrecognized stock-based compensation remained as of September 30, 2021.

Himalaya Therapeutics

Clinical Trial Agreement

In April 2022, the Company entered into a Clinical Trial Agreement with Himalaya Therapeutics SEZC. Under the agreement, Himalaya Therapeutics SEZC agreed to provide services related to the initiation of clinical trials for BA3011 in the People's Republic of China. For the first year following effectiveness of the agreement, the Company has agreed to pay Himalaya Therapeutics SEZC for the full-time use of two of its personnel. Payments are due and payable by BioAtla to Himalaya Therapeutics SEZC on a quarterly calendar basis and are non-refundable. For the three and nine months ended September 30, 2022 the Company recognized $0.1 million in research and development expense related to the Clinical Trial Agreement. The Company did not have any amounts due from or due to Himalaya Therapeutics SEZC as of September 30, 2022.

10. 401(k) Plan

The Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. The Company, at its discretion, may make certain matching contributions to the 401(k) plan. As of September 30, 2022 and December 31, 2021, the Company had not made any matching contributions.

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

You should read the following discussion and analysis together with our unaudited condensed consolidated financial statements and notes thereto included in "Item 1. Financial Statements" of this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2021 included in the Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or the SEC, on February 28, 2022. In addition to historical information, this Quarterly Report contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption "Risk Factors" in the Annual Report, and the caption "Risk Factors" in this Quarterly Report, as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Furthermore, past operating results are not necessarily indicative of results that may occur in future periods.

Overview

We are a clinical-stage biopharmaceutical company developing our novel class of highly specific and selective antibody-based therapeutics for the treatment of solid tumor cancer. Our CABs capitalize on our proprietary discoveries with respect to tumor biology, enabling us to target known and widely validated tumor antigens that have previously been difficult or impossible to target. Our novel CAB therapeutic candidates exploit characteristic pH differences between the tumor microenvironment and healthy tissue. Unlike healthy tissue, the tumor microenvironment is acidic, and we have designed our antibodies to selectively bind to their targets on tumor cells under acidic pH conditions but not on targets in normal tissues. Our approach is to identify the necessary targeting and potency required for cancer cell destruction, while aiming to eliminate or greatly reduce on-target, off-tumor toxicity—one of the fundamental challenges of existing cancer therapies.

We are a United States-based company with research facilities in San Diego, California and, through our contractual relationship with BioDuro-Sundia, a provider of preclinical development services, in Beijing, China. Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials of our product candidates, including the ongoing Phase 2 clinical trials of mecbotamab vedotin and ozuriftamab vedotin and our Phase 1 clinical trial of BA3071, establishing and maintaining our intellectual property portfolio, manufacturing clinical and research material through third parties, hiring personnel, establishing product development and commercialization collaborations with third parties, raising capital and providing general and administrative support for these operations. Since 2014, such research and development activities have exclusively related to the research, development, manufacture and Phase 1 and Phase 2 clinical testing of our CAB antibody-based product candidates and the strengthening of our proprietary CAB technology platform and pipeline.

We have incurred significant losses to date. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current and future product candidates. Our net losses were $25.8 million and $78.9 million for the three and nine months ended September 30, 2022, respectively, compared to $22.9 million and $72.0 million for three and nine months ended September 30, 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $265.3 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We do not expect to generate meaningful revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating expenses for the foreseeable future due to the cost of research and development, including identifying and designing product candidates and conducting preclinical studies and clinical trials, and the regulatory approval process for our product candidates. We expect our expenses, and the potential for losses, to increase as we conduct clinical trials of our lead product candidates and seek to expand our pipeline.

We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities as we:

- advance the clinical development of mecbotamab vedotin;
- advance the clinical development of ozuriftamab vedotin;
- advance the clinical development of BA3071;
- expand our pipeline of bispecific and other CAB antibody-based product candidates;
- continue to invest in our CAB technology platform;
- maintain, protect and expand our intellectual property portfolio, including patents, trade secrets and know-how;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish additional product collaborations and commercial manufacturing relationships with third parties;

- build sales, marketing and distribution infrastructure and relationships with third parties to commercialize product candidates for which we may obtain marketing approval;
- continue to expand our operational, financial and management information systems; and
- attract, hire and retain additional clinical, scientific, management, administrative and commercial personnel.

As a result, we will require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings, collaborations and other similar arrangements. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to raise capital, maintain our research and development efforts, expand our business or continue our operations at planned levels, and as a result we may be forced to substantially reduce or terminate our operations.

As of September 30, 2022, our cash and cash equivalents totaled approximately $178.1 million. Based on our current operating plan, our current cash and cash equivalents are expected to be sufficient to fund our ongoing operations into the second half of 2024. However, we have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Impact of COVID-19 on Our Business

The worldwide COVID-19 pandemic may affect our ability to complete our current preclinical studies and clinical trials, initiate and complete our planned preclinical studies and clinical trials, disrupt regulatory activities or have other adverse effects on our business, results of operations, financial condition and prospects. In addition, the pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could adversely affect our business, operations and ability to raise funds to support our operations. To date, we have experienced modest business disruptions, including with respect to clinical trials we are conducting, and non-material impairments as a result of the pandemic. Our mecbotamab vedotin Phase 2 sarcoma trial remains on schedule and the Phase 2 interim analysis for mecbotamab vedotin NSCLC and ozuriftamab vedotin studies have experienced some modest delays. We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. In March 2020, we implemented a remote working policy for many of our employees and began restricting non-essential travel. During 2022 we modified our hybrid work policy to allow for more flexibility based on department needs and travel requirements. We are complying with all applicable guidelines for our clinical trials, including remote clinical monitoring. In April 2020, we borrowed $0.7 million under the Paycheck Protection Program under the CARES Act and we received full loan forgiveness from the U.S. Small Business Association in July 2021, resulting in the recognition of $0.7 million to other income for the twelve months ended December 31, 2021. We are continuing to monitor the potential impact of the pandemic, but we cannot be certain what the overall impact will be on our business, financial condition, results of operations and prospects.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from the sale of products and do not expect to generate meaningful revenue in the near future.

In 2019 we entered into a collaboration agreement with BeiGene, Ltd. The agreement was amended several times and was terminated in November 2021, which resulted in the Company assuming responsibility for development of BA3071. We received a total of $25.0 million in non-refundable payments from BeiGene from this collaboration. Pursuant to the terms of the November 2021 amendment, we agreed to pay single digit royalties to BeiGene and agreed to share on a limited basis in any upfront and milestone payments, if received, through a sublicense of BA3071. In addition, we may in the future seek third-party collaborators or joint venture partners for development and commercialization of additional CAB product candidates. We did not recognize any collaboration revenue for the three or nine months ended September 30, 2022 and 2021.

Prior to developing our own programs, we received revenue from services performed under fixed price service contracts that, in some cases, provided for potential milestone and royalty payments to us. We did not recognize any revenue from our legacy service

contracts for the three and nine months ended September 30, 2022. For the three and nine months ended September 30, 2021 we recognized $0 and $0.3 million in revenues from our legacy service contracts, respectively.

Operating Expenses

Research and Development

Research and development expenses consist primarily of costs incurred in the discovery and development of our product candidates.

- External expenses consist of:
  - Fees paid to third parties such as contractors, clinical research organizations (CROs) and consultants, and other costs related to preclinical and clinical trials;
  - Fees paid to third parties such as contract manufacturing organizations (CMOs) and other vendors for manufacturing research and clinical trial materials; and
  - Expenses related to laboratory supplies and services.
- Unallocated expenses consist of:
  - Personnel-related expenses, including salaries, benefits and equity-based compensation expenses, for personnel in our research and development functions; and
  - Related equipment and facilities depreciation expense.

We expense research and development costs in the periods in which they are incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and services are performed.

We expect our research and development expenses to generally increase for the foreseeable future as we continue to invest in research and development activities to advance our product candidates and our clinical programs and expand our product candidate pipeline. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. Successful product 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. Accordingly, to the extent that our product candidates continue to advance into clinical trials, including larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, the quality and consistency in their manufacture, investment in our clinical programs and competition with other products. As a result of these variables, we are unable to determine the duration and completion costs of our research and development projects and programs or when and to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative

Our general and administrative expenses include personnel-related expenses for personnel in our executive, finance, corporate and other administrative functions, intellectual property and patent costs, facilities and other allocated expenses, other expenses for outside professional services, including legal, human resources, investor relations, audit and accounting services and insurance costs. Personnel-related expenses consist of salaries, benefits and equity-based compensation. We also expect our general and administrative expenses to increase in the future as we increase our personnel headcount to support our research and development activities to advance our product candidates and clinical stage programs.

Interest Income

Interest income consists primarily of interest earned on our cash and cash equivalent balances. Our interest income has not been significant to date and we do not expect any material changes.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

(in thousands)	Three Months Ended September 30, 2022	2021	Change
Collaboration and other revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	19,839	$ 16,553	$ 3,286
General and administrative	6,340	7,142	(802)
Total operating expenses	26,179	23,695	2,484
Loss from operations	(26,179)	(23,695)	(2,484)
Other income (expense):			
Interest income	370	76	294
Interest expense	—	—	—
Gain on extinguishment of debt	—	690	(690)
Other income	30	(1)	31
Total other income (expense)	400	765	(365)
Consolidated net loss and comprehensive loss	$ (25,779)	$ (22,930)	$ (2,849)

Research and Development Expense

The following table summarizes our research and development expenses allocated by CAB program for the periods indicated:

(in thousands)	Three Months Ended September 30, 2022	2021	Change
External expenses:			
BA3011 (AXL-ADC)	$ 4,227	$ 3,851	$ 376
BA3021 (ROR2-ADC)	2,807	2,982	(175)
Other CAB Programs	7,775	5,675	2,100
Total external expenses	14,809	12,508	2,301
Personnel and related	2,788	2,014	774
Equity-based compensation	1,427	1,267	160
Facilities and other	815	764	51
Total research and development expenses	$ 19,839	$ 16,553	$ 3,286

Research and development expenses were $19.8 million and $16.6 million for the three months ended September 30, 2022 and 2021, respectively. The increase of approximately $3.3 million was primarily driven by a $4.7 million increase in clinical development for our clinical-stage programs, a $0.8 million increase in personnel related costs due to an increase in headcount to support ongoing development activities for our programs, and a $0.2 million increase in stock-based compensation due to awards issued in connection with our 2020 Equity Incentive Plan, offset by a $2.1 million decrease in pre-clinical development and manufacturing costs for various programs.

General and Administrative Expense

General and administrative expenses were $6.3 million and $7.1 million for the three months ended September 30, 2022 and 2021, respectively. The decrease of approximately $0.8 million was primarily driven by a $0.9 million decrease in stock-based compensation related to awards issued under our 2020 Equity Incentive Plan, and a $0.2 million decrease in audit and legal services, offset by an increase of $0.3 million in personnel related expenses.

Interest Income

Interest income was $370,000 and $76,000 for the three months ended September 30, 2022 and 2021, respectively. The increase of $294,000 was due to higher yields earned during Q3 2022 compared to the same period in 2021.

Comparison of the Nine Months Ended September 30, 2022 and 2021

(in thousands)	Nine Months Ended September 30, 2022	2021	Change
Collaboration revenue	$ —	$ 250	$ (250)
Operating expenses:			
Research and development	57,473	$ 41,826	$ 15,647
General and administrative	22,107	31,376	(9,269)
Total operating expenses	79,580	73,202	6,378
Loss from operations	(79,580)	(72,952)	(6,628)
Other income (expense):			
Interest income	601	254	347
Interest expense	—	(3)	3
Gain on extinguishment of debt	—	690	(690)
Other income	40	(1)	41
Total other income	641	940	(299)
Consolidated net loss and comprehensive loss	$ (78,939)	$ (72,012)	$ (6,927)

Research and Development Expense

The following table summarizes our research and development expenses allocated by CAB program for the periods indicated:

(in thousands)	Nine Months Ended September 30, 2022	2021	Change
External expenses:			
BA3011 (AXL-ADC)	$ 12,505	$ 13,633	$ (1,128)
BA3021 (ROR2-ADC)	6,839	8,365	(1,526)
Other CAB Programs	23,732	9,485	14,247
Total external expenses	43,076	31,483	11,593
Personnel and related	7,992	4,907	3,085
Equity-based compensation	4,125	3,376	749
Facilities and other	2,280	2,060	220
Total research and development expenses	$ 57,473	$ 41,826	$ 15,647

Research and development expenses were $57.5 million and $41.8 million for the nine months ended September 30, 2022 and 2021, respectively. The increase of $15.6 million was primarily driven by a $12.9 million increase in clinical development for our clinical-stage programs, a $3.1 million increase in personnel related costs due to an increase in headcount to support ongoing development activities for our programs, a $0.7 million increase in stock-based compensation due to awards issued in connection with our 2020 Equity Incentive Plan, and a $0.3 million increase in facility and other allocated costs, offset by a $1.4 million overall decrease in pre-clinical development and manufacturing costs for various programs.

General and Administrative Expense

General and administrative expenses were $22.1 million and $31.4 million for the nine months ended September 30, 2022 and 2021, respectively. The decrease of $9.3 million was primarily driven by an $11.0 million decrease in stock-based compensation related to awards issued under our 2020 Equity Incentive Plan, including the modification of awards in 2021 that were issued to one of our co-founders, and a $0.2 million decrease in personnel related expenses, offset by an increase of $1.0 related to a legal settlement, a $0.7 million increase in audit and legal services and a $0.2 million increase in travel related expenses.

Interest Income

Interest income was $601,000 and $254,000 for the nine months ended September 30, 2022 and 2021, respectively. The increase of $347,000 was due to higher yields earned compared to the same period in 2021.

Liquidity and Capital Resources

We have incurred aggregate net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of September 30, 2022, we had cash and cash equivalents of $178.1 million.

Debt

On April 22, 2020, we received proceeds from a loan pursuant to the Paycheck Protection Program of the CARES Act, "the PPP Loan", in the amount of $0.7 million from City National Bank, as lender. In July 2021, we were notified by our lender that our PPP Loan had been fully forgiven by the U.S. Small Business Administration and that there was no remaining balance on the PPP Loan. We recorded the forgiveness as other income in July 2021.

Future Funding Requirements

Our primary uses of cash are to fund operating expenses, which consist primarily of research and development expenses related to our programs and related personnel costs. The timing and amount of future funding requirements depends on many factors, including the following:

- the initiation, scope, rate of progress, results and costs of our preclinical studies, clinical trials and other related activities for our product candidates;
- the costs associated with manufacturing our product candidates and establishing commercial supplies and sales, marketing and distribution capabilities;
- the timing and costs of capital expenditures to support our research and development efforts;
- the number and characteristics of other product candidates that we pursue;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;
- the timing, receipt and amount of sales from our potential products;
- our need and ability to hire additional management, scientific and medical personnel;
- the effect of competing products that may limit market penetration of our product candidates;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing and success of any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the compliance and administrative costs associated with being a public company; and
- the extent to which we acquire or invest in businesses, products or technologies, although we have no commitments or agreements relating to any of these types of transactions.

Based on our current operating plan, our current cash and cash equivalents are expected to be sufficient to fund our ongoing operations into the second half of 2024. However, we have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

In addition, we will require additional funding in order to complete development of our product candidates and commercialize our products, if approved. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We cannot assure you that, in the event we require additional financing, such financing will be available at acceptable terms to us, if at all. Failure to generate sufficient cash flows from operations, raise additional capital, and reduce discretionary spending should additional capital not become available could have a material adverse effect on our ability to achieve our intended business objectives. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical studies and clinical trials. To the extent that we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates. We may also have to forego future revenue streams of research programs at an earlier stage of development or on less favorable terms than we would otherwise choose, or have to grant licenses on terms that may not be favorable to us. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. For example, market volatility

resulting from a variety of causes, including the COVID-19 pandemic, supply chain disruptions, and geopolitical disruptions, including the recent conflict between Russia and Ukraine, could adversely impact our ability to access capital as and when needed. We may choose to raise additional capital through the issuance of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to our investors and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, acquiring other businesses, products or technology, or declaring dividends. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delay, scale back or stop certain research and development programs.

Cash flows

The following summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (66,073)	$ (41,265)
Investing activities	(234)	(835)
Financing activities	(552)	73,420
Net increase (decrease) in cash and cash equivalents	$ (66,859)	$ 31,320

Cash Used in Operating Activities

Net cash used in operating activities totaled $66.1 million for the nine months ended September 30, 2022, which consisted of a consolidated net loss of $78.9 million, a net change of $0.9 million in our operating assets and liabilities and $12.0 million of non-cash transactions. The net change in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of $4.1 million, partially offset by an increase in prepaid expenses and other assets of $2.9 million. The non-cash transactions primarily consisted of $11.1 million of stock-based compensation and non-cash charges of $0.9 million related to depreciation and amortization.

Net cash used in operating activities for the nine months ended September 30, 2021 was $41.3 million, which consisted of a consolidated net loss of $72.0 million, a net change of $9.1 million in our operating assets and liabilities and $21.6 million of non-cash transactions. The net change in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of $10.8 million, offset by an increase in prepaid expenses and other assets of $1.5 million and $0.2 million of deferred rent. The non-cash transactions primarily consisted of $21.3 million of stock-based compensation and non-cash charges of $1.0 million related to depreciation and amortization, offset by the $0.7 million gain on the extinguishment of our PPP loan.

Cash Used in Investing Activities

Cash used in investing activities was $0.2 million for the nine months ended September 30, 2022 and $0.8 million for the nine months ended September 30, 2021, respectively, related to the purchase of property and equipment.

Cash Used in Financing Activities

Net cash used in financing activities was $0.6 million for the nine months ended September 30, 2022, which consisted primarily of the payment of taxes related to the net settlement of restricted stock units.

Net cash used in financing activities was $73.4 million for the nine months ended September 30, 2021, which consisted primarily of the proceeds from the issuance of common stock through a Private Placement of $75.0 million, the proceeds from the issuance of common stock under our Employee Stock Purchase Plan of $0.2 million, and $0.1 million due to the exercise of stock options under our Equity Incentive Plan, partially offset by our payment of initial public offering costs of $1.9 million.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and

liabilities at the date of the financial statements, as well as the reported revenue generated, and reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions.

Our critical accounting policies are those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. For a description of our critical accounting policies, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates" contained in our Annual Report on Form 10-K for the year ended December 31, 2021. There have not been any material changes to the critical accounting policies discussed therein during the nine months ended September 30, 2022.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. We had cash and cash equivalents of $178.1 million and $245.0 million as of September 30, 2022 and December 31, 2021, respectively, which consisted of bank deposits and money market funds. Such interest-bearing instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

We do not enter into investments for trading or speculative purposes and we do not currently utilize derivative financial instruments to manage our interest rate exposure. We have not historically been exposed to material risks due to changes in interest rates.

Foreign Currency Exchange Risk

Our contracts with customers are primarily denominated in U.S. dollars, with a small amount denominated in foreign currencies. As such, fluctuations in foreign currency exchange rates may cause us to recognize transaction gains and losses in our statement of operations. To date, foreign currency transaction gains and losses have not been material to our condensed consolidated financial statements, and we have not engaged in any foreign currency hedging transactions.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, 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 quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be subject to various claims and suits arising in the ordinary course of business. We are not currently a party to any legal proceedings the outcome of which we believe, if determined adversely to us, would individually or in the aggregate have a material adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors.

Risk Factor Summary

Investing in our common stock involves a high degree of risk. You should carefully consider all information in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes appearing elsewhere in this report and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before purchasing our common stock. These risks are discussed more fully in the section titled "Risk Factors." These risks and uncertainties include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and we have a history of significant losses and expect to continue to incur significant losses for the foreseeable future.
- We will require substantial additional capital to finance our operations, and if we fail to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Our product candidates may fail in development or suffer delays that adversely affect their commercial viability.
  We are substantially dependent on the success of our patented CAB technology platform, and our future success depends heavily on the successful development of this platform.
- We may expend our resources to pursue particular product candidates and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.
- The market may not be receptive to our product candidates because they are based on our novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates.
- Results from early-stage clinical trials may not be predictive of results from late-stage or other clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.
- Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data.
- Delays in the commencement and completion of clinical trials could increase costs and delay or prevent regulatory approval and commercialization of our product candidates.
- We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms.
- We may be unable to obtain U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.
- We intend to seek approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways, if available, and if we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.
- Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.
- If we fail to attract and retain qualified senior management and key scientific personnel, our business may be materially and adversely affected.
- If we are unable to establish sales, marketing and distribution capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved, effectively in the United States and foreign jurisdictions or generate product revenue.

- A portion of our research and development activities take place in China, and uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, a trade war, deterioration of international relations, or political unrest in China could materially adversely affect our business, financial condition and results of operations.
- We face risks related to health epidemics and outbreaks, including the COVID-19 pandemic, which could significantly disrupt our preclinical studies and could affect enrollment of patients in our clinical trials. Continuation and increasing severity of these conditions could delay or prevent our receipt of necessary regulatory approvals.
- If we fail to enter into collaborations with third parties for the development and commercialization of certain of our product candidates, or if our current and future collaborations are not successful, we may not be able to capitalize on the market potential of our patented technology platform and resulting product candidates.
- If we are not able to obtain, maintain and protect our intellectual property rights in any product candidates or technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, third parties could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market.
- Intellectual property rights of third parties could prevent or delay our drug discovery and development efforts and could adversely affect our ability to commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to discover, develop or market our product candidates.
- The future issuance of equity or of debt securities that are convertible into equity will dilute our share capital.
- Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval and their interests may conflict with your interests as an owner of our common stock.

Risk Factors

Risks related to our financial position and need for additional capital

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have a history of significant losses and we expect to continue to incur significant losses for the foreseeable future, which together with our limited operating history, makes it difficult to assess our future viability.

We are a Phase 2 clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale and have not generated any revenue from product sales. Since the commencement of our operations, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies and clinical trials of our product candidates, including the ongoing Phase 2 clinical trials of mecbotamab vedotin and ozuriftamab vedotin, establishing and maintaining our intellectual property portfolio, manufacturing clinical and research material through third parties, hiring personnel, establishing product development and commercialization collaborations with third parties, raising capital and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to assess our future viability than it could be if we had a longer operating history.

We have incurred significant losses to date. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our current and future product candidates. Our net losses were $95.4 million and $35.9 million for the years ended December 31, 2021 and 2020, respectively. For the nine months ended September 30, 2022 and 2021, our net losses were $78.9 million and $72.0 million, respectively. As of September 30, 2022, we had an accumulated deficit of $265.3 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We do not expect to generate meaningful revenue from product sales for the foreseeable future, and we expect to continue to incur significant operating expenses for the foreseeable future due to the cost of research and development, including identifying and designing product candidates and conducting preclinical studies and clinical trials, and the regulatory approval process for our product candidates. We expect our expenses, and the potential for losses, to increase substantially as we conduct clinical trials of our lead product candidates and seek to expand our pipeline, and as a result of macroeconomic factors, including inflation. For example, recently, several of our vendors have passed along price increases they have experienced in their own business as a result of inflation.

However, the amount of our future expenses and potential losses is uncertain. Our ability to achieve profitability, if ever, will depend on, among other things, our successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms and potentially

establishing a sales and marketing organization or suitable third-party alternatives to commercialize any approved product. If we, or our existing or future collaborators, are unable to develop and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.

The development of biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for mecbotamab vedotin, ozuriftamab vedotin and BA3071 and advance our other programs. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other comparable foreign regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of September 30, 2022, we had approximately $178.1 million in cash and cash equivalents. Based on our current operating plan, our current cash and cash equivalents are expected to be sufficient to fund our ongoing operations into the second half of 2024. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We plan to use our existing cash and cash equivalents to fund the research and development of our product candidates and development programs and to fund working capital and other general corporate purposes. Advancing the development of our product candidates will require a significant amount of capital. Our existing cash and cash equivalents may not be sufficient to fund any of our product candidates through regulatory approval. Because the length of time and activities associated with successful research and development of any individual product candidate are highly uncertain, we are unable to estimate the actual funds we will require for development, marketing approval and commercialization activities. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of our ongoing clinical trials for mecbotamab vedotin and ozuriftamab vedotin;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the clinical development efforts for BA3071;
- the progress of our collaborators with whom we have entered, or may in the future enter, into collaboration agreements and research and development agreements;
- the timing and amount of milestone payments we may receive under our collaboration agreements;
- our ability to maintain our current licenses, collaboration and research and development programs or possibly establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the cost and timing of regulatory approvals; and
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company.

If we are unable to obtain funding on a timely basis, including under our current or future collaborations, or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We cannot assure you that such financing will be available at acceptable terms to us, if at all. Failure to generate sufficient cash flows from operations, raise additional capital, and reduce discretionary spending should additional capital not become available could have a material adverse effect on our ability to

achieve our intended business objectives. To the extent that we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates. We may also have to forego future revenue streams of research programs at an earlier stage of development or on less favorable terms than we would otherwise choose or have to grant licenses on terms that may not be favorable to us. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Our financial condition could be adversely affected by general conditions in the global economy and in the global financial markets. For example, global financial crises have caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as a global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, licensing product rights, entering into product development collaborations, acquiring other businesses, products or technology or declaring dividends. If we are unable to obtain additional funding from these or other sources, it may be necessary to significantly reduce our rate of spending through reductions in staff and delay, scale back or stop certain research and development programs.

Risks related to the discovery, development and commercialization of our product candidates

Our current product candidates are in various stages of development. Our product candidates may fail in development or suffer delays that adversely affect their commercial viability. If we or our existing or future collaborators are unable to complete development of, obtain regulatory approval for or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We have no products on the market and our product candidates are in various stages of development. We are currently conducting Phase 2 clinical trials of mecbotamab vedotin and ozuriftamab vedotin; we have begun dosing patients in our Phase 1 trial of BA3071 and various other product candidates are in earlier stages of development. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and, if approved, successfully commercializing our product candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety, efficacy, purity and potency of our product candidates. In addition, the FDA may not agree with our clinical trial plans. For example, we have initiated potentially registrational Phase 2 trials for mecbotamab vedotin in treatment-refractory sarcoma patients. Based on recent FDA written responses, we are initiating part 2 of our phase 2 trial in undifferentiated pleomorphic sarcoma (UPS) and anticipate study enrollment to commence by year end. However, we cannot assure you that the FDA will agree that the results from this trial or other trials will be sufficient to support approval of any of our product candidates. For example, the objective response rates on our primary endpoints may not be sufficient, or there may be limitations with the total sample size of our studies and dose selection strategy. Any product candidate can unexpectedly fail at any stage of preclinical or clinical development and the historical failure rate for product candidates is high. The results from preclinical testing of a product candidate may not predict the results that will be obtained in later clinical trials of the product candidate. We or our existing or future collaborators may experience issues that delay or prevent clinical testing and regulatory approval of, or our ability to commercialize, product candidates, including, among others:

- delays in our clinical trials resulting from factors including those related to the COVID-19 pandemic;
- negative or inconclusive results from preclinical testing or clinical trials leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by participants in clinical trials or by individuals using therapeutic biologics that share characteristics with our product candidates;
- delays in submitting INDs or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators or institutional review boards, or IRBs, to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities, including the EMA, regarding the scope or design of clinical trials;
- delays in enrolling patients in clinical trials;
- high drop-out rates of patients;
- inadequate drug materials or other supplies necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness of our product candidates during clinical trials;

- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- deficiencies in our third-party manufacturers' manufacturing processes or facilities;
- success or further approval of competitor products approved in indications in which we undertake development of our product candidates, which may change the standard of care or change the standard for approval of our product candidates in our proposed indications;
- failure of any third-party contractors, investigators or contract research organizations, or CROs, to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology or product candidates in particular; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies, including the EMA.

Because CABs represent a new generation of antibodies, a delay or failure in development of any CAB product candidate could represent a major set-back for our patented technology platform and for our company generally.

We are substantially dependent on the success of our patented CAB technology platform, and our future success depends heavily on the successful development of this platform.

We use our CAB technology platform to develop product candidates for cancer therapies. Any failures or setbacks involving our CAB technology platform, including adverse events, could have a detrimental impact on all of our product candidates and our research pipeline. For example, we may uncover a previously unknown risk associated with CABs or other issues that may be more problematic than we currently believe, which may prolong the period of observation required for obtaining, necessitate additional clinical testing or result in the failure to obtain, regulatory approval. If our CAB technology is not safe in certain product candidates, we could be required to abandon or redesign all of our current product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to use and expand our patented CAB technology platform to continue to build a pipeline of product candidates and develop marketable products.

We are using our patented technology platform to develop CABs in oncology indications with our lead product candidates mecbotamab vedotin and ozuriftamab vedotin, as well as continuing to build our pipeline of product candidates. Our business depends not only on our ability to successfully develop, obtain regulatory approval for, and commercialize the product candidates we currently have in clinical and preclinical development, but to continue to generate new product candidates through our platform. Even if we are successful in continuing to build our pipeline and further progress the clinical development of our current product candidates, any additional product candidates may not be suitable for clinical development, including as a result of harmful side effects, manufacturing issues, limited efficacy or other characteristics that indicate that they are unlikely to be products that will succeed in clinical development, receive marketing approval or achieve market acceptance. If we cannot validate our technology platform by successfully commercializing CAB product candidates, we may not be able to obtain product, licensing or collaboration revenue in future periods, which would adversely affect our business, financial condition, results of operations and prospects.

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

As a result of our limited financial and managerial resources, we must make strategic decisions as to which targets and product candidates to pursue and may forego or delay pursuit of opportunities with other targets or product 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 products or profitable market opportunities. Failure to properly assess potential product candidates could result in our focus on product candidates with low market potential, which would harm our business, financial condition, results of operations and prospects. Our spending on current and future research and development programs and product candidates for specific targets or indications may not yield any commercially viable products. Our understanding and evaluation of biological targets for the discovery and development of new CAB product candidates may fail to identify challenges encountered in subsequent preclinical and clinical development. If we do not accurately evaluate the likelihood of clinical trial success, commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product 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.

If the market opportunities for any product that we develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We focus our product candidate development on therapeutic CAB antibodies for the treatment of various oncology indications, such as soft tissue and bone sarcoma, NSCLC, melanoma, ovarian cancer, and head and neck cancer among others. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, physician interviews, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. In addition, the subset of patients that are likely to respond to our product candidates, as identified by our quantitative biomarker assay/Target Membrane Percent Score ("TmPS"), may not correspond with and may be smaller than what market data may indicate. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

The market may not be receptive to our product candidates because they are based on our novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates.

The product candidates that we are developing are primarily based on our patented CAB technology platform, which uses new technologies to create our novel therapeutic approach. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt a product or treatment based on our patented technology platform, and we may not be able to convince patients, the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our product candidates;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority, including the EMA;
- the willingness of patients to obtain biopsies to determine the TmPS score for treatment eligibility;
- relative convenience and ease of administration of our product candidates;
- the willingness of patients to accept any new methods of administration;
- the success of any physician education programs;
- the availability of adequate government and third-party payor reimbursement;
- the pricing of our products, particularly as compared to alternative treatments; and
- availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

If any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Results from early-stage clinical trials may not be predictive of results from late-stage or other clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

Positive and promising results from preclinical studies and early-stage clinical trials may not be predictive of results from late-stage clinical trials or from clinical trials of the same product candidates for the treatment of other indications. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Late-stage clinical trials could differ in significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen and statistical design. Moreover, success in clinical trials in a particular indication does not guarantee that a product candidate will be successful for the treatment of other indications. Many companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials after achieving encouraging or positive results in early-stage development. We cannot assure you that we will not face similar setbacks in our ongoing or planned clinical trials, including in our Phase 2 clinical trials of mecbotamab vedotin for the treatment of soft tissue and bone

sarcoma and for the treatment of refractory NSCLC, in our Phase 2 clinical trial of ozuriftamab vedotin for the treatment of refractory melanoma and NSCLC and in any subsequent or post-marketing confirmatory clinical trials.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA will agree with our clinical trial plans. For example, we have initiated potentially registrational Phase 2 trials for mecbotamab vedotin in treatment-refractory sarcoma patients. Based on recent FDA written responses, we are initiating part 2 of our phase 2 trial in undifferentiated pleomorphic sarcoma (UPS) and anticipate study enrollment to commence by year end. However, we cannot assure you that the FDA will agree that the results from this trial or other trials will be sufficient to support approval of any of our product candidates. For example, the objective response rates on our primary endpoints may not be sufficient, or there may be limitations with the total sample size of our studies and dose selection strategy. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

Furthermore, while multi-center investigator-initiated clinical trials of mecbotamab vedotin and ozuriftamab vedotin in patients with platinum-resistant ovarian cancer started to enroll patients in Canada in 2022, we do not control the design or administration of these or any other investigator-initiated trials that may be conducted, nor the submission or approval of any IND or foreign equivalent required to conduct any such trials. Any investigator-initiated trials could, depending on the actions of such third parties, jeopardize the validity of the clinical data generated, identify significant concerns with respect to our product candidates that could impact our findings or clinical trials, and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities. To the extent the results of this or other investigator-initiated trials are inconsistent with, or different from, the results of our ongoing or planned company-sponsored trials or raise concerns regarding our product candidates, the FDA or a foreign regulatory authority may question the results of the company-sponsored trial, or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such foreign regulatory authorities may require us to obtain and submit additional clinical data, which could delay clinical development or marketing approval of our product candidates. In addition, while investigator-initiated trials could be useful to inform our own clinical development efforts, there is no guarantee that we will be able to use the data from these trials to form the basis for regulatory approval of our product candidates.

Preliminary, preplanned interim and topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and/or are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, preplanned interim or topline data from our clinical trials. These data and related findings and conclusions may only reflect certain endpoints rather than all endpoints and are subject to change. For example, we may report tumor responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data 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, topline data should be viewed with caution until the final data are available. In addition, we may report preplanned interim analyses of the clinical trials we may complete, which 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. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary preplanned interim or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Delays in the commencement and completion of clinical trials could increase costs and delay or prevent regulatory approval and commercialization of our product candidates.

We cannot guarantee that clinical trials of our product candidates will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of the clinical trial process, and other events may cause us to temporarily or permanently stop a clinical trial. Events that may prevent successful or timely commencement and completion of clinical development include:

- negative preclinical data;
- delays in receiving the required regulatory clearance from the appropriate regulatory authorities to commence clinical trials or amend clinical trial protocols, including any objections to our INDs or protocol amendments from the FDA;
- delays in reaching, or a failure to reach, a consensus with regulatory authorities on study design;
- delays in reaching, or failure to reach, agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulties in obtaining IRB approval at each site;
- challenges in recruiting suitable patients to participate in a trial;
- the inability to enroll a sufficient number of patients in clinical trials to ensure adequate statistical power to detect statistically significant treatment effects;
- difficulties in having patients complete a trial or return for post-treatment follow-up;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a clinical trial;
- unforeseen safety issues, including occurrence of treatment emergent adverse events, or TEAEs, associated with the product candidate that are viewed to outweigh the product candidate's potential benefits;
- difficulties in adding new clinical trial sites;
- ambiguous or negative interim results;
- lack of adequate funding to continue the clinical trial;
- difficulties in manufacturing sufficient quantities of product candidate acceptable for use in clinical trials in a timely manner, or at all; or
- the COVID-19 pandemic, which continues to adversely affect the pace of patient enrollment in clinical trials, also has caused clinical sites to redirect personnel and resources to focus on immediate and often unplanned numbers and needs of COVID-19 patients. In addition, the pandemic may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Our clinical trial results may not be successful, or even if successful, may not lead to regulatory approval.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate, leading to delays in our development timelines. For example, we may face difficulty enrolling a sufficient number of patients in a timely manner in our clinical trials for mecbotamab vedotin and ozuriftamab vedotin due to the limited number of suitable patients meeting the required AXL or ROR2 tumor membrane expression levels.

Patient enrollment and retention in clinical trials depends on many factors, including the size and nature of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, delays in enrollment due to travel or quarantine policies, or other factors, related to the COVID-19 pandemic or other epidemics or pandemics, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, including criteria related to biomarkers, our ability to obtain and maintain patient consents, including any additional consents necessary for enrollment of adolescent patients, and our ability to successfully complete prerequisite studies before enrolling certain patient populations. Furthermore, any negative results or new safety signals we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials we are conducting. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we rely on clinical trial sites to ensure timely conduct of our clinical trials and, while we have entered into agreements governing their services, we are limited in our ability to compel their actual performance.

Our product candidates may cause undesirable and unforeseen side effects or have other properties impacting safety that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Undesirable side effects caused by our product candidates 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 and potential product liability claims. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial. Many compounds developed in the biopharmaceutical industry that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented their further development. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

In our clinical trials for mecbotamab vedotin and ozuriftamab vedotin, we have observed adverse events such as reversible myelosuppression, transient liver enzyme elevations, pyrexia, or fever, metabolic disturbances and peripheral neuropathy.

For our current and future clinical trials, we have contracted with and expect to continue to contract with CROs experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, they may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials and which could jeopardize regulatory approval.

Further, clinical trials by their nature test product candidates in only samples of the potential patient populations. With a limited number of patients and limited duration of exposure in such trials, rare and severe side effects of our product candidates may not be uncovered until a significantly larger number of patients are exposed to the product candidate. For example, while we believe that mecbotamab vedotin and ozuriftamab vedotin have demonstrated manageable tolerability profiles thus far, we cannot assure you that these and our other product candidates will not cause more severe side effects in a greater proportion of patients.

In addition, mecbotamab vedotin and ozuriftamab vedotin are being studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with mecbotamab vedotin, ozuriftamab vedotin or our other product candidates may also be undergoing surgical, radiation or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials.

The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, some of the late-stage patients enrolled in our mecbotamab vedotin and ozuriftamab vedotin clinical trials may die or experience major clinical events either during the course of our clinical trials or after participating in such trials due mainly to the gravity of their illness, which has occurred in the past.

In the event that any of our product candidates receive regulatory approval, and we or others later identify undesirable and unforeseen side effects caused by such product, negative consequences, including any of the following, could occur:

- regulatory authorities may suspend, limit or withdraw their approval of such product, or seek an injunction against its manufacture or distribution;
- we may be required to conduct additional clinical trials or post-approval studies;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a REMs and/or create a Medication Guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our product candidates prove to be unsafe, our business, financial condition, results of operations and prospects may be materially and adversely affected.

We are developing certain of our product candidates in combination with other therapies, and regulatory approval, safety or supply issues with these other therapies may delay or prevent the development and approval of our product candidates.

Currently, we are evaluating the use of each of mecbotamab vedotin and ozuriftamab vedotin in combination with an anti-PD-1 inhibitor and plan to evaluate the use of BA3071 in combination with an anti-PD-1 inhibitor. In the future, we may explore the use of these or our other product candidates in combination with other therapies. If we choose to develop a product candidate for use in combination with an approved therapy, we are subject to the risk that the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions could revoke approval of, or that safety, efficacy, manufacturing or supply issues could arise with, the therapy used in combination with our product candidate. If the therapies we use in combination with our product candidates are replaced as the standard of care, the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our product candidates, if approved, being removed from the market or being less successful commercially.

Where we develop a product candidate for use in combination with a therapy that has not been approved by the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions, we will not be able to market our product candidate for use in combination with such an unapproved therapy, unless and until the unapproved therapy receives regulatory approval. It is expected that BA3071 will also be evaluated in combination with an anti-PD-1 antibody in late stage development for solid tumor patients. In addition, other companies may also develop their products or product candidates in combination with the unapproved therapies with which we are developing our product candidates for use in combination. Any setbacks in these companies' clinical trials, including the emergence of serious adverse effects, may delay or prevent the development and approval of our product candidates.

If the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions do not approve or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain regulatory approval of or to commercialize such product candidates in combination with these therapies.

If safe and effective use of any of our product candidates, such as mecbotamab vedotin and ozuriftamab vedotin, depends on a companion diagnostic test, then the FDA generally will require approval or clearance of that companion diagnostic at the same time that the FDA approves our product candidates, if at all. If we are unable to successfully develop companion diagnostic tests for our product candidates, experience significant delays in doing so, rely on third parties in the development of such companion diagnostic tests, or do not obtain or face delays in obtaining FDA approval of a companion diagnostic test, the full commercial potential of our product candidates and our ability to generate revenue will be materially impaired.

We are exploring predictive biomarkers to determine patient selection for our clinical trials. Specifically, to help inform which patients may be most suitable for treatment with mecbotamab vedotin and ozuriftamab vedotin, we have developed a quantitative biomarker assay that has been validated in accordance with CLIA requirements, the TmPS, which measures AXL and ROR2 expression levels on the tumor membrane. We are using both AXL and ROR2 TmPS scores in our ongoing clinical trials and they may be used for patient selection in future clinical trials. If the AXL and ROR2 TmPS scores prove to be a useful method for patient selection, we will incorporate the specific diagnostic test into our potentially registrational studies and have partnered with a diagnostic provider to codevelop a companion diagnostic.

If use of a companion diagnostic test is essential for the safe and effective use of any of our product candidates, such as mecbotamab vedotin and ozuriftamab vedotin, then the FDA generally will require approval or clearance of that companion diagnostic at the same time that the FDA approves our product candidates, if at all. The FDA has generally required in vitro companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a PMA for that diagnostic simultaneously with approval of the therapeutic. The process of obtaining or creating such diagnostic and obtaining PMA approval is time-consuming and costly and a delay in diagnostic approval could delay drug approval. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. On April 13, 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on our companion diagnostic development and strategy. This guidance and future policies from the FDA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. We may be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and adversely affect our business, financial condition, results of operations and prospects.

We expect to rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that require such tests. If the FDA, EMA or a comparable foreign regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after it obtains marketing approval, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. If we or our third-party collaborators experience any delay in developing or obtaining regulatory approval of a companion diagnostic, we may be unable to enroll enough patients for our current and planned clinical trials, the development of our product candidates may be adversely affected or we may not obtain marketing approval, and we may not realize the full commercial potential of our product candidates, including mecbotamab vedotin and ozuriftamab vedotin.

We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.

The development and commercialization of drugs and therapeutic biologics is highly competitive. We compete with a variety of multinational biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors have developed, are developing and will develop product candidates and processes competitive with our product candidates. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are developing product candidates. We believe that while our patented CAB technology platform, its associated intellectual property and our scientific and technical know-how give us a competitive advantage in this space, competition from many sources remains. Our success will partially depend on our ability to develop and protect therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective or less expensive than the therapeutics we develop.

Although we do not believe competing companies have selective CAB technology, there is a wide array of activity in multiple areas of immune-based cellular therapies for oncology including CAR-T and T-cell receptor therapies. Certain companies are also

pursuing antibody therapies in immuno-oncology, ADCs and various prodrug biologic products designed to be preferentially activated at tumor sites. There are several FDA approved ADC products and several companies in various stages of clinical development of ADCs mostly directed at oncology indications, a key feature of our product candidates mecbotamab vedotin and ozuriftamab vedotin. There are also companies developing technologies designed to deliver biologics and chemotherapeutic agents with some targeting capabilities. In addition, if any of our product candidates are approved in oncology indications, they may compete with existing biologics and small molecule therapies, or may be used in combination with existing therapies. There are also many other therapies under development that are intended to treat the same cancers that we are targeting or may target with our CAB platform, including through approaches that could prove to be more effective, have fewer side effects, be cheaper to manufacture, be more convenient to administer or have other advantages over any products resulting from our technologies.

Many of our competitors, either alone or with strategic partners, have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. In addition, our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, less toxic or more convenient than products we may develop. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of our products' entry. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Our biologic product candidates for which we intend to seek approval may face competition through an abbreviated pathway.

The ACA includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our product candidates.

There is a risk that any product candidates we may develop that are approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider any product candidates we may develop to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated.

Our business entails a significant risk of product liability, and if we are unable to obtain sufficient insurance coverage, such failure could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We expect to be exposed to significant product liability risks inherent in the development, testing and manufacturing of our product candidates and products, if approved. Product liability claims could delay or prevent completion of our development

programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our third-party manufacturer's manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, including limitations on the approved indications for which our product candidates may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. In addition, we may be subject to liability based on the actions of our existing or future collaborators in connection with their development of products using our CAB technology. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks related to regulatory approval and other legal compliance matters

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.

Our product candidates are subject to extensive governmental regulations relating to, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed in the United States and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, lengthy, time-consuming, uncertain and subject to unanticipated delays. We have not previously submitted a BLA to the FDA, or similar drug approval filings to comparable foreign regulatory authorities, for any product candidate, and it is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us or our existing or future collaborators to begin selling them.

We have not completed any large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate, and numerous other factors including the substantial discretion of regulatory authorities. The standards that the FDA and its foreign counterparts, including the EMA, use when regulating us and our existing or future collaborators require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

In addition, our product candidates could 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 product candidate is safe, pure and potent for its proposed indication;
- the results of clinical trials may fail to achieve the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- we may be unable to demonstrate that the dose for the product candidate has been optimized;
- we may be unable to demonstrate a sufficient response rate or duration of response for a product candidate;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data submitted in support of regulatory approval;
- the data collected from preclinical studies and clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other regulatory submission necessary to obtain regulatory approval in the United States or elsewhere; and

- we or our contractors may not meet the current Good Manufacturing Practices, or cGMPs, and other applicable requirements for manufacturing processes, procedures, documentation and facilities necessary for approval by the FDA or comparable foreign regulatory authorities.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving a BLA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

We intend to seek approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways, if available. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We intend to seek accelerated approval for mecbotamab vedotin and ozuriftamab vedotin, and we may seek accelerated approval for one or more of our other product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. We intend to seek accelerated approval for some of our product candidates on the basis of objective response rate, a surrogate endpoint that we believe is reasonably likely to predict clinical benefit. For products granted accelerated approval, post-marketing confirmatory trials are required to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence, and the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. If we were to pursue accelerated approval for a product candidate for a disease or condition, we would do so on the basis that there is no available therapy for that disease or condition. If any of our competitors were to receive full approval on the basis of a confirmatory trial for a drug for a disease or condition for which we are seeking accelerated approval before we receive accelerated approval, the disease or condition would no longer qualify as one for which there is no available therapy, and accelerated approval of our product candidate would not occur. Many cancer therapies rely on accelerated approval, and the treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. We cannot assure you that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, we cannot assure you that after subsequent FDA feedback we will continue to pursue accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, we cannot assure you that such application will be accepted or that any expedited

development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type.

Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. In addition, Congress is considering various proposals to potentially make changes to the accelerated approval pathway, including proposals to increase the likelihood of withdrawal of approval in such circumstances.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, 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 products.

Any regulatory approvals that we or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to 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 product candidate. Furthermore, any regulatory approval to market a product may be subject to limitations on the labeling of the product or may require safety warnings or other restrictions. In addition, the FDA has the authority to require a REMS plan as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product 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 cGMPs and the FDA's Good Clinical Practices, or GCP, for any clinical trials that we conduct post-approval. The manufacturer and manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. Later discovery of previously unknown problems with a product, 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 product;
- withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- delay of approval or refusal by the FDA or comparable regulatory authorities in other jurisdictions to approve pending applications or supplements to approved applications filed by us, our current collaborator or any future strategic partners;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; 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 product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If these regulations impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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 and we may not achieve or sustain profitability, which would adversely affect our business, financial condition, results of operations and prospects.

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

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government authorities, private health insurers and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products. If the price we are able to charge for any products we develop, or the reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. For example, in the United States, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. 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.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our existing or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

There may be significant delays in obtaining reimbursement for newly-approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs or therapeutic biologics, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower-cost drugs or therapeutic biologics that

are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics 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 or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected, and our ability to commercialize such products, once approved, could be materially impaired.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, if we receive marketing approval for mecbotamab vedotin as a treatment for soft tissue and bone sarcoma, physicians may nevertheless use our product for their patients in a manner that is inconsistent with the approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. Moreover, although we believe that our product candidates may be safer or more effective than other therapies, unless we conduct head-to-head comparative studies, we will not be able to make any claims of superiority. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition, results of operations and prospects.

Disruptions at the FDA, the SEC and other government agencies caused by, among other factors, funding shortages or global health concerns, could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of the Securities and Exchange Commission, or SEC, and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, notably in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020 and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 20, 2020, the FDA announced its intention to resume certain domestic on-site inspections, subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. In addition, on April 15, 2021, the FDA issued a guidance document in which the FDA outlined plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical or is otherwise limited by travel restrictions, but where the FDA determines that a remote evaluation would still be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic.

Additionally, as of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. On July 16, 2020, the FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or

delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. We cannot assure you that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

Our employees, independent contractors, principal investigators, CROs, consultants, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, suppliers and vendors 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 violates: (i) FDA laws and regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (ii) manufacturing standards, (iii) federal and state healthcare fraud and abuse laws and regulations or (iv) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, 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, which could result in regulatory sanctions and serious harm to our reputation. 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 be in compliance with such laws or regulations. 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 material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions, including exclusion from government healthcare programs, and serious harm to our reputation.

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

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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 and we may not achieve or sustain profitability.

For example, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both the government and private insurers and significantly impacted the U.S. pharmaceutical industry. Among other things, the ACA intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. By way of example, the ACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program, imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole," which is now 70% of the negotiated price. There have been executive, legislative and judicial efforts to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. For example, the Tax Cuts and Jobs Act, among other things, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on

procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how the any future challenges to the ACA and the healthcare reform measures of the Biden administration will impact the ACA and our business. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, and a reduction to the sequestration cut to 1% from April 1, 2022 to June 30, 2022, due to the COVID-19 pandemic. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations. Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Furthermore, on September 9, 2021, the Biden administration published a wide-ranging list of policy proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. It is unclear to what extent other statutory, regulatory, and administrative initiatives will be enacted and implemented, and to what extent these or any future legislation or regulations by the Biden administration will have on our business, including market acceptance, and sales, of our products and product candidates.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Beilina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

At the state level, individual states are increasingly aggressive in passing legislation and implementing 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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal 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 reduced demand

for our current product candidates and any future product candidates or additional pricing pressures. It is possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that QHP issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers were facing responding to the COVID-19 virus.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the U.S. federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, or HITECH, which imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers;
- the U.S. Physician Payments Sunshine Act created under the ACA, and its implementing regulations, which require that certain manufacturers of drugs, devices, medical supplies and therapeutic biologics that are reimbursable under Medicare, Medicaid, and Children's Health Insurance Programs report annually to the Department of Health and Human Services information related to certain payments and other transfers of value to physicians, as defined by such law, physician assistants, certain types of advance practice nurses and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require that pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation, or the GDPR, which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles and creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we possess and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. We comply with the GDPR and the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in United Kingdom national law, the latter regime having the ability to separately fine and penalize violations. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Ongoing developments in the United Kingdom have created additional uncertainty regarding personal data transfers from the European Economic Area (EEA) to the United Kingdom following the termination of the personal data transfer grace period set out in the EU and United Kingdom Trade and Cooperation Agreement, which ended on June 30, 2021. It is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. Moreover, in July 2020 the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield) under which personal data could be transferred from the EEA and the United Kingdom to entities in the United States who had self-certified under the Privacy Shield scheme. This has led to uncertainty about the adequate transfer mechanisms for other personal data transfers from the EEA and the United Kingdom to the United States or interruption of such transfers. In the event that any court of law orders the suspension of personal data transfers to or from a particular jurisdiction this could give rise to operational interruption in the performance of services for customers, greater costs to implement alternative data transfer mechanisms that are still permitted, regulatory liabilities or reputational harm. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information, and such laws may differ from each other, all of which may complicate compliance efforts. For example, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Additionally, although not effective until January 1, 2023, the CPRA, which expands upon the CCPA, was passed in the November 2020 election. The CCPA has created new individual privacy rights and places increased privacy and security obligations on entities handling personal information. The CPRA significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. The CCPA and CPRA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare, privacy and securities laws and regulations worldwide will involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to regulatory investigations and enforcement actions, as well as civil private plaintiff litigation, which could mean significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from participation in government-funded healthcare programs such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, imprisonment, reputational harm and diminished profits. Responding to regulatory inquiries and defending against any actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties that could materially harm our business.

Even if we receive marketing and commercialization approval of a product candidate, we will be subject to continuing regulatory requirements, including in relation to adverse patient experiences with the product and clinical results that are reported after

a product is made commercially available, both in the United States and any foreign jurisdiction in which we seek regulatory approval. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturer and manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. We rely, and expect we will continue to rely, on third-party manufacturers, and we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunctions, civil penalties and criminal prosecution.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We and our third-party contractors must comply with environmental, health and safety laws and regulations. A failure to comply with these laws and regulations could expose us to significant costs or liabilities.

We and our third-party contractors are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages, fines and penalties associated with such liability which could exceed our assets and resources.

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 biological or hazardous materials or wastes arising out of and in the course of employment, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks related to employee matters, managing our growth and other risks related to our business

If we fail to attract and retain qualified senior management and key scientific personnel, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We are highly dependent upon members of our senior management, including Jay M. Short, Ph.D., our Chairman and Chief Executive Officer and Scott Smith, our President, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, the initiation and completion of our planned clinical trials or the commercialization of product candidates or any future product candidates.

Competition for qualified personnel in the pharmaceutical, biopharmaceutical and biotechnology field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

We currently have no sales organization. If we are unable to establish sales, marketing and distribution capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved, effectively in the United States and foreign jurisdictions or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize our product candidates in the United States and foreign jurisdictions on our own, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our product candidates receives regulatory approval, we will need to develop internal sales, marketing and distribution capabilities to commercialize such products, which would be expensive and time-consuming, or make arrangements with third parties to perform these services. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products or decide to co-promote products with existing or future collaborators, we will need to establish and maintain marketing and distribution arrangements with third parties, and we cannot assure you that we will be able to enter into such arrangements on acceptable terms, or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties, and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

In order to successfully implement our development and commercialization plans and strategies, and operate as a public company, we expect to need additional development, managerial, operational, financial, sales, marketing and other personnel. Future growth would impose significant added responsibilities on members of management, including, among others:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory review process for mecbotamab vedotin and ozuriftamab vedotin and any other product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize mecbotamab vedotin, ozuriftamab vedotin and any future product candidates will depend, in part, on our ability to effectively manage any future growth,

and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

To date, we have used the services of outside vendors to augment our capabilities in performing certain tasks, including preclinical and clinical trial management, manufacturing, statistics and analysis and research and development functions. Our growth strategy may also entail expanding our group of such contractors or consultants to assist in implementing these tasks going forward. Because we rely on numerous consultants, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for mecbotamab vedotin, ozuriftamab vedotin and any future product candidates or otherwise advance our business. We may not be able to manage our existing outside contractors or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize mecbotamab vedotin, ozuriftamab vedotin and any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may violate (intentionally or unintentionally) our internal processes and procedures, or engage in misconduct or other illegal activity. Such actions could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (1) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, including cGMP requirements, (3) data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify, prevent and deter these activities and/or 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 be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such actions, including fraud or other misconduct, even if none occurred. If any such actions are instituted against us, we may incur significant costs to respond, and if we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We depend on our information technology systems and those of our CROs, manufacturers, contractors and consultants. Our internal computer systems, or those of any of our CROs, manufacturers, other contractors, consultants, existing or future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use or acquisition of or destruction of our proprietary and confidential data, employee data or personal data, which could result in additional costs, loss of revenue significant liabilities, harm to our reputation and material disruption of our operations.

In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. Despite the implementation of security measures, our internal computer systems and infrastructure and those of our current and any future CROs, manufacturers, other contractors, consultants, existing or future collaborators and other third-party service providers are vulnerable to unauthorized access, impairment, or damage from various methods, including cybersecurity attacks, ransomware attacks, breaches, intentional or accidental mistakes or errors, or other technological failures, which can include, among other things, computer viruses, malware, exploit of unpatched product or service vulnerabilities, unauthorized access attempts (including third parties gaining access to systems using stolen or inferred credentials), denial-of-service attacks, phishing attempts, service disruptions, natural disasters, fire, terrorism, war and telecommunication and electrical failures. As the cyber-threat landscape evolves, these attacks are growing in frequency, levels of persistence, sophistication and intensity, are becoming increasingly difficult to detect, and are being conducted by sophisticated groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely,

which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. If such an event were to occur and cause interruptions in our operations, impact to critical data or systems, or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy, cybersecurity or data protection laws such as HIPAA, HITECH, the CCPA and GDPR), it could result in a material disruption of our product candidate development programs and our business operations and we could incur significant liabilities. There also could be requirements that we notify individuals and regulators in the event of unauthorized access to, acquisition, destruction, alteration, or misuse of, personal or health information, which could result from breaches experienced by us or by our vendors, contractors or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs, and result in the loss of confidence by our partners, customers, and stakeholders, and thereby have longer term adverse impact on our business operations and revenue. For example, the loss of clinical trial data from completed, ongoing or future clinical trials involving our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. In addition, because of our approach of running multiple clinical trials in parallel, any breach of our computer systems may result in a loss of data or compromised data integrity across many of our programs in various stages of development.

We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed and we could be subject to significant fines or penalties for any noncompliance with certain state, federal or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

A portion of our research and development activities take place in China. Uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, a trade war, deterioration of international relations, or political unrest in China could materially adversely affect our business, financial condition and results of operations.

We conduct preclinical research and development activities in China through BioDuro-Sundia, which is U.S. owned, but governed by Chinese laws, rules and regulations. Additionally, our agreement with Himalaya Therapeutics Limited Company is for the initiation of clinical trials of BA3021 in the People’s Republic of China. The Chinese legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. In addition, the Chinese legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or not published at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation. Any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in U.S. or EU legal systems.

Furthermore, we are exposed to the possibility of disruption of our research and development activities in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China, including the escalation of tensions between China and Taiwan, such as recent step up of military exercises around Taiwan by China. In addition, disagreements between the United States and China with respect to their political, military or economic policies toward Taiwan may contribute to further controversies. For example, a trade war could lead to increased costs for clinical materials that are manufactured in China. These interruptions or failures and any restrictive measures resulting from a deterioration of U.S.- China relations could also result in impeding the commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. These uncertainties may impede our ability to enforce the contracts we have entered into and our ability to continue our research and development activities and could materially and adversely affect our business, financial condition and results of operations.

Our current operations are concentrated in two locations. We or the third parties upon whom we depend may be adversely affected by earthquakes, wildfires or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

A portion of our current operations are located in our facilities in San Diego, California, and we conduct a portion of our research and development activities in China through our arrangement with BioDuro-Sundia. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or 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. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects. In addition, all of our therapeutic antibodies are manufactured by starting with cells which are stored in a one master cell bank for each antibody manufactured stored in multiple locations. While we believe we will have adequate backup should any cell bank be lost in a catastrophic event, and we take precautions when transporting our cell banks, it is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks.

Our business is subject to economic, political, regulatory and other risks associated with conducting business internationally.

We, our collaborators or licensees may seek regulatory approval of our product candidates outside of the United States including in China, the European Union, Australia, New Zealand, and Japan. We conduct preclinical research and development activities in China through BioDuro-Sundia, which is U.S. owned, but governed by Chinese laws. Additionally, pursuant to our agreement with Himalaya Therapeutics Limited Company, we conduct clinical trials in the People's Republic of China. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including, among others:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

Additionally, in February 2022, armed conflict escalated between Russia and Ukraine. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, greater regional instability, geopolitical shifts and other adverse effects on macroeconomic conditions, currency exchange rates, supply chains and financial markets. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face risks related to health epidemics and outbreaks, including the COVID-19 pandemic, which could significantly disrupt our preclinical studies and could affect enrollment of patients in our clinical trials. Continuation and increasing severity of these conditions could delay or prevent our receipt of necessary regulatory approvals.

We face risks related to health epidemics or outbreaks of communicable diseases. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a pandemic. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries, which in the case of COVID-19 has occurred. The COVID-19 pandemic has resulted in governments implementing numerous containment measures, such as travel bans and restrictions, particularly quarantines, shelter-in-place or total lock-down orders and business limitations and shutdowns. Some restrictions aimed at minimizing the spread of COVID-19 have been and may from time to time be eased or lifted in the U.S. and other countries; however, in response to local surges and new waves of infection, including those caused by the spread of the Delta, Omicron and other variants, some countries, states, and local governments have maintained or reinstituted these restrictions, or may reinstitute these restrictions from time to time, in response to rising rates of infection.

We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. During 2022 we modified our hybrid work policy to allow for flexibility based on department needs and travel requirements. We are complying with all applicable guidelines for our clinical trials, including remote clinical monitoring. We are continuing to monitor the potential impact of the pandemic, but we cannot be certain what the overall impact will be on our business, financial condition, results of operations and prospects.

In addition, the COVID-19 pandemic is having a severe effect on the clinical trials of many drug candidates of several sponsors. Some trials have been merely delayed, while others have been cancelled. The extent to which the COVID-19 pandemic may impact our preclinical and clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and geographic reach of the outbreak, the severity of COVID-19 (including its variant strains, such as the highly transmissible Delta and Omicron variants), the effectiveness of actions to contain and treat COVID-19 and the rate of vaccination and efficacy of approved vaccines against COVID-19 and its variant strains. To date, we have experienced modest business disruptions, including with respect to the clinical trials we are conducting, and non-material impairments as a result of the pandemic. The continued spread of COVID-19 could adversely impact our clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Disruptions or restrictions on our ability to travel to monitor data from our clinical trials, or to conduct clinical trials, or the ability of patients enrolled in our studies to travel, or the ability of staff at study sites to travel, as well as temporary closures of our facilities or the facilities of our clinical trial partners and their contract manufacturers, would negatively impact our clinical trial activities. In addition, we rely on independent clinical investigators, CROs and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, including the collection of data from our clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our preclinical trials could be delayed and/or disrupted by the COVID-19 pandemic. As a result, the expected timeline for data readouts of our preclinical studies and clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks related to our dependence on third parties

We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of certain of our product candidates. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our patented technology platform and resulting product candidates.

We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of certain of our product candidates. In addition, we may in the future seek third-party collaborators or joint venture partners for development and commercialization of additional CAB product candidates. With respect to our collaborations, and what we expect will be the case with any future license or collaboration agreements, we have, and would expect to have, limited control over the amount and timing of resources that our existing or future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our existing or

future collaborators' willingness to select additional product candidates to license and their abilities and willingness to fulfill their payment obligations and successfully perform the functions assigned to them in these arrangements.

Our existing collaboration arrangements currently pose, and future collaborations involving our product candidates will pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical or clinical trial results, changes in the collaborators' strategic focus due to their acquisition of competitive products or their internal development of competitive products, available funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators and other alliances could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidate, particularly if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidate or that result in costly litigation or arbitration that diverts management attention and resources;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations;
- collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding our out-licensed product candidates;
- collaborations may be terminated and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates; and
- collaborators' sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If our existing or future collaborators cease development efforts under our existing or future collaboration agreements, or if any of those agreements are terminated, we may lose committed funding under those agreements and these collaborations may fail to lead to commercial products and the reputation of our patented CAB technology platform may suffer.

Revenue from research and development collaborations depend upon continuation of the collaborations, initiation and expansion of the number of programs subject to the collaborations, the achievement of milestones and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve

milestones, revenue and cash resources from milestone payments under our existing or future collaboration agreements will be substantially less than expected.

Our ability to advance our product candidates may be limited by third parties on which we rely for certain technologies which we use in certain of our programs. If any third party developing our product candidates or other candidates based on our patented CAB technology platform experiences a delay or failure in development, regulatory approval or commercialization, even if such failure is not due to our CAB technology, it could reflect negatively on us, our other product candidates and our patented CAB technology platform. In addition, if one of our current or future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities and our stock price could be adversely affected.

We may not be successful in establishing commercialization collaborations, which could adversely affect our ability to commercialize our product candidates, if approved.

From time to time, we may evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. Moreover, such arrangements are complex and time-consuming to negotiate, document and implement and they may require substantial resources to maintain.

In addition, it is possible that a collaborator may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in its commercialization efforts, in which event the commercialization of such product candidates could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not be favorable to us or may not be perceived as favorable, which may negatively impact our business, financial condition, results of operations and prospects.

If third parties on which we rely to conduct our preclinical and clinical trials, do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development programs could be delayed with material and adverse effects on our business, financial condition, results of operations and prospects.

We rely, and expect we will continue to rely, on third-party investigators, CROs, data management organizations and consultants to conduct, supervise and monitor our ongoing clinical trials and preclinical studies. We currently rely on third parties to manage and conduct our clinical trials of mecbotamab vedotin, ozuriftamab vedotin and BA3071. Because we rely on these third parties and do not have the ability to conduct preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants are not our employees and we will have limited control over the amount of time and resources that they dedicate to our development programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our development programs. The third parties with whom we contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we do not contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our development programs could be delayed and otherwise adversely affected. Furthermore, we depend on the availability of various animals to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development or to continue clinical development, including pharmacological and toxicology evaluations. There is currently a global shortage of animals available for drug development, due in part to an increase in demand from companies and other institutions developing vaccines and treatments for COVID-19. This has caused the cost of obtaining animals for our preclinical studies to increase dramatically, and if the shortage continues, could also result in delays to our development timelines. In all events, we are responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan, protocols for the trial and regulatory requirements. The FDA requires preclinical studies to be conducted in accordance with GLPs and clinical trials to be conducted in accordance with GCPs, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies and clinical trials could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We rely on third parties for the manufacture of our product candidates for preclinical studies and our ongoing clinical trials, and we expect to continue to do so for additional clinical trials and ultimately commercialization. This reliance on third parties

increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We rely, and expect we will continue to rely, on third-party contract manufacturers to manufacture our preclinical and clinical trial product supplies and the raw materials used to create our product candidates. We do not own manufacturing facilities for producing such supplies, and we do not have long-term manufacturing agreements. Furthermore, the raw materials for our product candidates may be sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. We cannot assure you that our preclinical and clinical development product supplies or raw materials will not be limited, interrupted, or be of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of a manufacturer could require significant effort and expertise because there are a limited number of qualified replacements. The technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates.

If we submit an application for regulatory approval of any of our product candidates, the facilities used by our contract manufacturers to manufacture our product candidates will be subject to inspection by the FDA or other regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others or if they are unable to maintain a compliance status acceptable to the FDA or other regulatory authorities, approval of our product candidates may be delayed or we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including, among others:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

In addition, we have no material long-term contracts with our suppliers, and we compete with other companies for raw materials and production. We may experience a significant disruption in the supply of raw materials from current sources or, in the event of a disruption, we may be unable to locate alternative materials suppliers of comparable quality at an acceptable price, or at all. In addition, if we experience significant increased demand, or if we need to replace an existing supplier, we may be unable to locate additional supplies of raw materials on terms that are acceptable to us, or at all, or we may be unable to locate any supplier with sufficient capacity to meet our requirements or to fill our orders in a timely manner. Identifying a suitable supplier is an involved process that requires us to become satisfied with their quality control, responsiveness and service, financial stability and labor and other ethical practices. Even if we are able to expand existing sources, we may encounter delays in production and added costs as a result of the time it takes to train suppliers in our methods, products and quality control standards.

The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production. If we or any of our third-party manufacturers encounter any loss of materials or if any of our third-party manufacturers encounter other difficulties, or otherwise fail to comply with their contractual or regulatory obligations, our ability to provide product candidates for clinical trials or our products to patients, once approved, the development or commercialization of our product candidates could be delayed or stopped.

The manufacture of biotechnology products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and our contract manufacturers must comply with cGMPs, regulations and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. In order to conduct clinical trials of our product candidates, we and existing and future collaborators will need to manufacture them in large quantities and in accordance with cGMPs. Manufacturers of biotechnology products often encounter difficulties in production, particularly in scaling up and validating initial production. In addition, if microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Delays in raw materials availability and supply may also extend the period of time required to develop our products. Furthermore, changes in our manufacturing methods may require comparability studies, including clinical bridging studies, which may result in delays to the approval process for our product candidates.

All of our therapeutic antibodies are manufactured by starting with cells which are stored in a cell bank. We have one master cell bank for each antibody manufactured in accordance with cGMPs, which is stored in multiple locations. We are currently creating multiple working cell banks. While we believe we will have adequate backup should any cell bank be lost in a catastrophic event, and we take precautions when transporting our cell banks, it is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks.

We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. For example, the extent to which the COVID-19 pandemic impacts the ability to procure sufficient supplies for the development of our product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products or enforcement actions by regulatory authorities. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products and could have an adverse effect on our business, financial condition, results of operations and prospects.

Risks related to intellectual property

If we are not able to obtain, maintain and protect our intellectual property rights in any product candidates or technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, third parties could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to develop and manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. The patent process is expensive and time-consuming, and we may not be able to apply for patents on certain aspects of our product candidates in a timely fashion, at a reasonable cost, in all jurisdictions, or at all. Our existing issued and granted patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable or that any issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors.

Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual issues. We will be able to protect our proprietary rights from unauthorized use by third parties only to the

extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our patent claims.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against granted patents. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted patent claims thus attacked, or may lose the allowed or granted claims altogether. As of November 2021, there is an ongoing patent opposition proceeding regarding our patent EP2 406 399 at the European Patent Office which is related to a version of methods used for evolving and screening potential product candidates. The Opposition Division revoked EP2 406 399 in its decision dated March 10, 2020 and we filed an appeal on July 20, 2020. In addition, we cannot assure you that:

- We may obtain, maintain, protect and enforce intellectual property protection for our technologies and product candidates.
- Others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license.
- We or our licensors, or our existing or future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license.
- We or our licensors, or our existing or future collaborators are the first to file patent applications covering certain aspects of our inventions.
- Others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- A third party may not challenge our patents and, if challenged, that a court would hold that our patents are valid, enforceable and infringed.
- Any issued patents that we own or have licensed will provide us with any competitive advantage, or will not be challenged by third parties.
- We may develop or in-license additional proprietary technologies that are patentable.
- Pending patent applications that we own or may license will lead to issued patents.
- The patents of others will not have a material or adverse effect on our business, financial condition, results of operations and prospects.
- Our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our commercial markets.

If the breadth or strength of protection provided by the patents and patent applications we hold, obtain or pursue with respect to our product candidates is challenged, or if they fail to provide meaningful exclusivity for our product candidates, it could threaten our ability to practice our technologies or commercialize our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Furthermore, an interference or derivation proceeding can be provoked by a third party or instituted by a patent office or in a court proceeding, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

Where we obtain licenses from third parties, in some circumstances, we may 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. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

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

In addition to seeking patent protection for certain aspects of our product candidates, we also consider trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We seek to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. 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. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. 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 from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position could be harmed.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. Competitors could willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies 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, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, 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' products, others may be able to exploit our product candidates and discovery technologies to identify and develop competing product candidates, and thus our competitive position could be adversely affected, as could our business.

The terms of our patents may not protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years after its earliest U.S. non-provisional effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies or product candidates are obtained, once the patent life has expired, we may be open to competition. Our issued patents will expire on dates ranging from 2030 to 2037, subject to any additional patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2030 to 2043 plus any potential patent extensions that may be available for such patents. Due to the amount of time required for the development, testing and regulatory review of new product 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 sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to

expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request or require. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request or require, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In September 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether another party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art render our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and the provision of additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of the application of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard applied in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution and defense of our or our licensors' patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product 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 involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, sometimes narrowing the scope of patent protection available in certain circumstances, weakening the rights of patent owners in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, 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 the patents we might obtain or license in the future.

Other companies or organizations may challenge our or our licensors' patent rights or may assert patent rights that prevent us from developing and commercializing our products.

CAB therapeutics are a new scientific field. We have obtained grants and issuances of CAB therapeutic patents and the various technologies used in discovering and producing CAB therapeutic proteins. The issued patents and pending patent applications in the United States and in key markets around the world that we own or license claim many different methods, compositions and processes relating to the discovery, development, manufacture and commercialization of antibody and immunoregulatory therapeutics. Specifically, we own a portfolio of patents, patent applications and other intellectual property covering CAB compositions of matter as well as their development and methods of use.

As the field of antibody and immunoregulatory therapeutics matures, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse effect on our business, financial condition, results of operations and prospects or our ability to successfully compete.

There are many issued and pending patents that claim aspects of our product candidates and modifications that we may need to apply to our product candidates. There are also many issued patents that claim antibodies or portions of antibodies that may be relevant for CAB products we wish to develop. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may not be able to market products or perform research and development or other activities covered by these patents.

Intellectual property rights of third parties could prevent or delay our drug discovery and development efforts and could adversely affect our ability to commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to discover, develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing or otherwise violating the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation proceedings, post grant reviews, *inter partes* reviews, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Given the vast number of patents in our field of technology, we cannot assure you that marketing of our product candidates or practice of our technologies will not infringe existing patents or patents that may be granted in the future. Because the antibody landscape is still evolving and the CAB antibody landscape is a new field, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. There are numerous companies that have pending patent applications and issued patents broadly covering many aspects of antibodies generally or covering antibodies directed against the same targets as, or targets similar to, those we are pursuing. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or product candidates or elements thereof, or our manufacture or uses relevant to our development plans. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product or formulation itself, the holders of any such patents may be able to block our ability to commercialize such product candidate. In such cases, we may not be in a position to develop or commercialize products or product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further practice our technologies or develop and commercialize one or more of our product candidates. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our CAB technologies. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our CAB technologies. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, be forced to abandon our product candidates or seek a license from any patent holders, and would most likely be required to pay license fees or royalties or both, each of which could be substantial. No assurances can be given that a license will be available on commercially reasonable terms, if at all. Even if we were able to obtain a license, the rights we obtain may be nonexclusive, which would provide our competitors access to the same intellectual property rights upon which we are forced to rely. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates or technologies may give rise to claims of infringement of the patent rights of others.

We or our collaboration partner, or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. If we or our licensors, or any future strategic partners are found to infringe a

third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages, if we are found to have willfully infringed. In addition, we or our licensors, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our existing or future collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the United States, remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates or technologies could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products. Third-party intellectual property right holders may also actively bring infringement claims against us, even if we have received patent protection for our technologies and product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or our technologies so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may have ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful, and issued patents covering our product candidates could be found invalid or unenforceable if challenged in court in the United States or abroad.

Competitors may infringe our patents or the patents of our licensors. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could counterclaim that our patent is invalid or

unenforceable, or the court may refuse to stop the defendant in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

Interference or derivation proceedings provoked by third parties or brought by us, the USPTO or any foreign patent authority may be necessary to determine the priority and/or ownership of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. 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. 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.

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

Obtaining a valid and enforceable issued or granted patent covering our technology in the United States and worldwide can be extremely costly. In jurisdictions where we have not obtained patent protection, competitors may use our technology to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our future products in jurisdictions where we do not have issued or granted patents or where our issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly that relating to biopharmaceuticals. This could make it difficult for us to prevent the infringement of our patents or marketing of competing products in violation of our proprietary rights in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions, regardless of whether they are successful, could result in substantial cost and divert our efforts and attention from other aspects of our business. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

We generally file a provisional patent application first (a priority filing) at the USPTO. An international application under the Patent Cooperation Treaty, or PCT, is usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in the United States, Europe, Japan, Australia and Canada and, depending on the individual case, also in any or all of, *inter alia*, Brazil, China, Hong Kong, India, Israel, Mexico, New Zealand, Russia, South Africa, South Korea and other jurisdictions. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted in other jurisdictions. It is also quite common that depending on the country, various scopes of patent protection may be granted on the same product candidate or technology. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, 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 product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The requirements for patentability differ, in varying degrees, from country to country, and the laws of some foreign countries do not protect intellectual property rights, including trade secrets, to the same extent as federal and state laws of the United States. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business and results of operations may be adversely affected.

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.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.

Our current and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Moreover, collaboration arrangements are complex and time-consuming

to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. We also may be unable to license or acquire third-party intellectual property rights on terms that that would be favorable to us or would allow us to make an appropriate return on our investment. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us.

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 provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable law firms and other professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we in-license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our technologies and product candidates. While we will endeavor to try to protect our technologies and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We only have one currently registered trademark, and rely on common law protection for the rest of our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks related to our common stock

Our operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to annual and quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including, among others:

- variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- results of preclinical studies and clinical trials, or the addition or termination of clinical trials;
- the success of our existing collaborations and any potential additional collaborations, licensing or similar arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Our stock price may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been and is likely to continue to be highly volatile. The market price for our common stock may be influenced by many factors, including the other risks described in this section and the following:

- the timing and results of our clinical trials or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our current or future collaborators or our competitors, and the timing of these introductions or announcements;
- announcements of new collaboration agreements, or the restructuring or termination of current collaboration agreements;
- actions taken by regulatory agencies with respect to our products, preclinical studies, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including those regarding manufacturing, supply and commercialization of our products;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- the impact of any natural disasters or public health emergencies, such as the COVID-19 pandemic; and
- general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

The future issuance of equity or of debt securities that are convertible into equity will dilute our share capital.

We will need to raise additional capital in the future. To the extent we raise additional capital through the issuance of equity or convertible debt securities in the future, there will be further dilution to investors and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. We may choose to raise additional capital through the issuance of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock.

The dual class structure of our common stock and the option of the holder of shares of our Class B common stock to convert into shares of our common stock may limit your ability to influence corporate matters.

Our common stock has one vote per share, while our Class B common stock is non-voting. Nonetheless, each share of our Class B common stock may be converted at any time into one share of common stock at the option of its holder, subject to the limitations provided for in our amended and restated certificate of incorporation. Consequently, if holders of Class B common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our Class B common stock, and correspondingly decrease the voting power of the current holders of our common stock, which may limit your ability to influence corporate matters. Because our Class B common stock is generally non-voting, stockholders who own more than 10% of our Class B common stock and common stock overall but 10% or less of our common stock will not be required to report changes in their ownership from transactions in our Class B common stock pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and would not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act. In addition, acquisitions of Class B common stock would not be subject to notification pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

If securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading research or reports regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us, our business or our market. If no or few securities or industry analysts commence or maintain coverage of us, the trading price for our stock would be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to

publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval and their interests may conflict with your interests as an owner of our common stock.

As of September 30, 2022, executive officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own approximately 42.6% of our outstanding common stock. More specifically, Jay M. Short, Ph.D, our Chairman and Chief Executive Officer, together with his spouse, Carolyn Anderson Short, our former Chief of Intellectual Property and Strategy and Assistant Secretary, beneficially own approximately 8.0%, of our outstanding common stock, as of September 30, 2022.

As a result, Dr. Short and our other principal stockholders will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

In addition, we have entered into certain related party transactions with Himalaya Therapeutics SEZC, Inversagen, LLC and BioAtla Holdings, LLC, including various licensing arrangements with respect to certain CAB antibodies. Dr. Short and his wife, Carolyn Anderson Short, are each a manager of Inversagen, LLC and BioAtla Holdings, LLC and a director of Himalaya Therapeutics SEZC. In addition, Ms. Anderson Short is also an officer of Himalaya Therapeutics SEZC. These related party transactions, and any future related party transactions, create the possibility of actual conflicts of interest with regard to Dr. Short.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

All of our outstanding shares of common stock are freely tradable without restriction or further registration under the Securities Act unless held by our "affiliates" as defined in Rule 144 under the Securities Act, or Rule 144. Shares issued upon the exercise of stock options and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by Rules 144 and 701 under the Securities Act.

Certain holders of our outstanding shares have rights, subject to certain conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, which shares will be able to be sold in the public market upon issuance, subject to applicable securities laws and the lock-up agreements.

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 the amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. 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. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders be called only by the chairman of our board of directors, our chief executive officer, or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;

- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- a requirement that directors may only be removed "for cause" and only with 66 2/3% voting stock of our stockholders;
- a requirement that only the board of directors may change the number of directors and fill vacancies on the board;
- division of our board of directors into three classes, serving staggered terms of three years each; and
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders.

The Company's ability to attract and retain qualified members of our board of directors may be impacted due to new state laws, including recently enacted gender quotas.

In September 2018, California enacted SB 826 requiring public companies headquartered in California to maintain minimum female representation on their boards of directors as follows: by the end of 2019, at least one woman on its board, by the end of 2020, public company boards with five members will be required to have at least two female directors, and public company boards with six or more members will be required to have at least three female directors.

In September 2020, California enacted AB 979, which requires that by the end of 2021 California-headquartered public companies have at least one director on their boards who is from an underrepresented community, defined as "an individual who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, or Alaska Native, or who self-identifies as gay, lesbian, bisexual, or transgender."

In addition to that initial 2021 requirement, the law mandates that the number of directors from underrepresented communities be increased by the end of calendar year 2022, depending on the size of the board.

Each of these measures has been challenged in court, and although judges of the California Superior Court ruled that AB 979 and SB 826 violate the California constitution in April 2022 and May 2022, respectively, the Secretary of State of the State of California has appealed such rulings, and the ultimate enforceability of these or similar laws remains uncertain.

In addition, the Company is subject to the listing rules from Nasdaq related to board diversity and disclosure, which require all companies listed on Nasdaq's U.S. exchanges to publicly disclose consistent, transparent diversity statistics regarding their board of directors. Additionally, the rules require most Nasdaq-listed companies to have, or explain why they do not have, at least two diverse directors, including one who self-identifies as female and one who self-identifies as either an underrepresented minority or LGBTQ+.

Failure to achieve designated minimum gender and diversity levels in a timely manner exposes such companies to financial penalties and reputational harm. While we are currently in compliance with these regulations, we cannot assure that we can recruit, attract and/or retain qualified members of the board and meet gender and diversity quotas as a result of the California laws or Nasdaq rules, which may expose us to penalties and/or reputational harm.

We have incurred, and will continue to incur, significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices. Additionally, if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

As a public company, and particularly after we were no longer an emerging growth company or a smaller reporting company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, compared to our prior private company status, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and required us to accept reduced policy limits and coverage or to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more

difficult for us to attract and retain qualified members of our board of directors or our board committees or as executive officers. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

In addition, as a public company, we are required to incur costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We engaged outside consultants to assist in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have, and 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 our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting. As a result of the complexity involved in complying with the rules and regulations applicable to public companies, our management's attention may be diverted from other business concerns, which could harm our business, operating results, and financial condition. Since becoming a public company, we increased, and may in the future further increase, the number of employees dedicated to finance and reporting, and the services of outside consultants to meet requirements, which has increased our operating expenses. Beginning January 1, 2023, we will be a smaller reporting company and therefore, will no longer be required to include an attestation report on internal control over financial reporting by our independent registered public accounting firm for as long as we remain a smaller reporting company.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. Our internal control over financial reporting may not prevent or detect all errors and all fraud.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on The Nasdaq Global Market.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

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 and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such

litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns.

Our certificate of incorporation and bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of proceedings: (i) any derivative action or proceeding brought on behalf of our company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware or (iv) any action asserting a claim arising pursuant to any provision of our amended and restated certificate of incorporation or amended and restated bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum to the fullest extent permitted by law, for resolving any complaint asserting a cause of action arising under the Securities Act. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation and amended and restated bylaws 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 adversely affect our business and financial condition. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation and amended and restated bylaws described above.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds from Registered Securities

On December 15, 2020, the SEC declared effective our registration statement on Form S-1 (File No. 333-250093), as amended, filed in connection with our IPO. At the closing of the offering on December 18, 2020, we issued and sold 12,075,000 shares of our common stock at the initial public offering price to the public of $18.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares. We received gross proceeds from the IPO of $217.4 million, before deducting underwriting discounts and commissions of approximately $15.2 million and estimated offering costs of approximately $3.8 million.

As of September 30, 2022, we have used approximately $91.2 million of the proceeds from our IPO. There has been no material change in the planned use of such proceeds from that described in the final prospectus filed by us with the SEC on December 17, 2020.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Exhibit Filing Date	File/Furnished Herewith
10.1+	BioAtla, Inc. Management Change of Control Severance Plan and Summary Plan Description	8-K	001-39787	10.1	2022-09-21	
10.2*	Master Clinical Trial Collaboration Agreement, dated January 5, 2022, by and between BioAtla, Inc. and Bristol-Myers Squibb Company.					X
31.1	Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2†	Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1†	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.					X
101	The following materials from BioAtla's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, formatted in iXBRL (inline eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Stockholders' Equity (iv) the Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags					X
104	Cover Page Interactive Data File (formatted as Inline XBRL document and contained in exhibit 101)					X

† Furnished and not filed.

+ Indicates management contract or compensatory plan.

* Portions of this exhibit have been redacted in accordance with Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Company Name

Date: November 4, 2022

By: /s/ Jay M. Short, Ph.D.
Jay M. Short, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 4, 2022

By: /s/ Richard A. Waldron
Richard A. Waldron
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[***]."

MASTER CLINICAL TRIAL COLLABORATION AGREEMENT

THIS MASTER CLINICAL TRIAL COLLABORATION AGREEMENT (the "***Agreement***") is made and entered into as of as of the date signed by the last Party to sign below (the "***Effective Date***") by and between **BioAtla, Inc.**, headquartered at 11085 Torreyana Road, San Diego, California 92121 (the "***Company***"), and **Bristol-Myers Squibb Company**, headquartered at 430 E. 29th Street, 14FL, New York, New York. 10016 ("***BMS***"). The Company and BMS may be referred to herein individually as a "***Party***," or collectively as the "***Parties***."

RECITALS

WHEREAS, BMS is a biopharmaceutical company engaged in the research, development, manufacture and commercialization of human therapeutic products.

WHEREAS, the Company is a biopharmaceutical company engaged in the research, development, manufacture and commercialization of human therapeutic products.

WHEREAS, the Company and BMS desire to collaborate on clinical trials of separate combination therapies using two (2) of the Company's Conditionally Active Biologic Antibody Drug Conjugates known as BA3011 and BA3021, each in combination with BMS' PD-1 antagonist known as nivolumab.

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants contained herein, the Parties agree as follows.

Article 1
Definitions

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

"***Adverse Event***" ("***AE***"), "**Serious Adverse Event**" ("***SAE***"), and "***Serious Adverse Drug Reaction***" ("***SADR***") shall have the meanings provided to such terms in the International Conference on Harmonization ("***ICH***") guideline for industry on Clinical Safety Data Management (E2A, Definitions and Standards for Expedited Reporting).

"***Affiliates***" means, with respect to a Party, an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Person. As used in this section, the term "controls" (with correlative meanings for the terms "controlled by" or "under common control with") means (a) that an entity or company owns, directly or indirectly, more than fifty percent (50%) of the voting stock of another entity, or (b) that an entity, person or group otherwise has the actual ability to control and direct the management of the entity, whether by contract or otherwise.

"***Aggregate Safety Information***" means, with respect to a Party's Compound, the (a) Safety Information resulting from the Combined Therapy Study, plus (b) the Safety Information from all other clinical trials of such Compounds, whether alone or in combination with another pharmaceutical agent that necessitate amendments to

the protocols or informed consent forms for such trials that are required to be implemented by Regulatory Authorities, or are implemented by the applicable Party, in each case where, because of their severity, frequency or lack of reversibility, the other Party reasonably needs to know such Safety Information in order to ensure patient safety and prevent unreasonable risks in the conduct of the Combined Therapy Study (or that is otherwise included in the investigator's brochures for a Compound). Aggregate Safety Information shall be provided by a Party to the other Party in the same format as is contained in the investigator's brochures prepared by such Party for its Compound in each country where a Combined Therapy Study will be conducted.

"***Agilent***" means Agilent Technologies Denmark ApS (successor to Dako Denmark A/S).

"***Agreement***" has the meaning set forth in the preamble to this Agreement, as may be amended by the Parties from time to time in accordance with its terms.

"***Applicable Law***" means all applicable laws, rules and regulations (whether supranational, federal, state or local) that may be in effect from time to time and applicable to conduct under this Agreement, including (a) current Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP)), (b) applicable data protection and patient privacy laws and requirements (including those specified in the EU General Data Protection Regulation and the regulations issued under HIPAA), (c) export control and economic sanctions regulations that prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals, (d) anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials, representatives and third parties (including the United States Foreign Corrupt Practices Act), (e) laws and regulations governing payments to healthcare providers, (f) laws and requirements governing ineligibility to participate in federal, state or other healthcare programs (including debarment under 21 USC § 335a, disqualification under 21 CFR § 312.70 or § 812.119, sanctions by a Federal Health Care Program (as defined in 42 USC § 1320a-7b(f)), including the federal Medicare or a state Medicaid program), and (g) successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.

"***Arbitration Matter***" means any disputed matter that relates to or arises out of the validity, interpretation or construction of, or the compliance with or breach of, this Agreement; *provided* that such disputed matter has been considered, but not resolved, by the Executive Officers as set forth in Section 12.3. For clarity, no Publication Dispute, or any matter requiring mutual agreement of both Parties shall be an Arbitration Matter.

"***Bioanalysis Plan***" means the bioanalysis plan for any Samples as may be contemplated by the Combined Therapy Study Protocol or another subsequent written agreement between the Parties, as described in Section 7.8.

"***Biomarker Testing***" means [***].

"***BMS***" has the meaning set forth in the preamble to this Agreement.

"***BMS Compound***" means nivolumab. For avoidance of doubt, BMS Compound shall not include any biosimilar version of nivolumab (i.e., that is not proprietary to BMS or its Affiliates).

"***BMS Indemnitees***" has the meaning set forth in Section 10.2.

"***BMS Independent Patent Rights***" means any Patent Rights Controlled by BMS (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement that Cover the use (whether alone or in combination with other agents), manufacture, formulation or composition of matter of the BMS Compound and/or PD-L1 Expression Testing relating to use and administration of the BMS Compound.

"***BMS Regulatory Documentation***" means Regulatory Documentation (as defined below) relating to the BMS Compound.

"***BMS Study Data***" has the meaning set forth in Section 7.2.

"***BMS Study Invention***" means any Invention to the extent specifically relating to the BMS Compound (including compositions of matter or formulations of the BMS Compound and methods of use or manufacture of the BMS Compound as a monotherapy) and [***].

"***BMS Study Patents***" means any Patent Rights to the extent claiming any BMS Study Invention (and not claiming a Company Study Invention or Combined Therapy Invention).

"***BMS Technology***" means all Technology Controlled by BMS (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement related to the BMS Compound or the Combined Therapy and necessary for the conduct of a Combined Therapy Study. For clarity, BMS Technology includes the Technology for PD-L1 Expression Testing relating to use and administration of the BMS Compound but otherwise does not include (a) Inventions, (b) Study Data or (c) Combined Therapy Study Regulatory Documentation.

"***Bona Fide Collaborator***" means a Third Party engaged in a bona fide contractual licensing arrangement with a Party for a use or practice directly relating to one or more specific compounds or products that (a) are owned or controlled by such Party or such Third Party and (b) are the subject of a research, development or commercialization collaboration (as opposed to a license for a royalty or other consideration not involving a collaboration or a license to a service provider) between such Party and such Third Party.

"***Breaching Party***" shall have the meaning set forth in Section 11.2(a).

"***Business Day***" means a day other than Saturday, Sunday or any day on which both Parties conduct regular business operations at their respective headquarters.

"***Change of Control***" means , with respect to a Party (including any direct or indirect holding entity which directly or indirectly owns or otherwise controls at least fifty percent (50%) of the combined voting power of such Party (a "Parent Corporation")), (a) a merger or consolidation of such Party or Parent Corporation with a Third Party which results in the voting securities of such Party or Parent Corporation outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the owner of fifty percent (50%) or more of the combined voting power of such Party's or Parent Corporation's outstanding securities (other than through issuances by such Party or Parent Corporation of securities of such Party or Parent Corporation in a bona fide financing transaction or series of related bona fide financing transactions), or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's or Parent Corporation's assets or all or substantially all of such Party's or Parent Corporation's business to which this Agreement relates.

"***Clinical Hold***" means that (a) the FDA has issued an order to a Party pursuant to 21 CFR §312.42 to delay a proposed clinical investigation or to suspend an ongoing clinical investigation of the Combined Therapy or such Party's Compound in the United States or (b) a Regulatory Authority other than the FDA has issued an equivalent order to that set forth in (a) in any other country or group of countries.

"***Clinical Obligations Schedule***" means, for each Combined Therapy Study, the schedule incorporated within the Study Plan for such Combined Therapy Study setting forth the obligations of the Parties with respect to particular activities or obligations in connection with the conduct of the applicable Combined Therapy Study.

"***Combined Therapy***" means a therapy using either of the Company Compounds in combination with the BMS Compound, and, as applicable, an Other Therapy, in concomitant or sequenced combination or comparator use as individual formulations with or without another agent.

"***Combined Therapy IND***" has the meaning set forth in Section 2.1(f).

"***Combined Therapy Invention***" means any Invention that is not a BMS Study Invention or Company Study Invention.

"***Combined Therapy Patent***" means Patent Rights to the extent claiming any Combined Therapy Invention.

"***Combined Therapy Study Data***" has the meaning set forth in Section 7.2.

"***Combined Therapy Study***" or "***Study***" has the meaning set forth in Section 2.1(a).

"***Combined Therapy Study Regulatory Documentation***" means any Regulatory Documentation to be submitted for the conduct of the Combined Therapy Study, but excluding (a) any Regulatory Documentation that is Company Technology and (b) any Regulatory Documentation that is BMS Technology.

"***Commercially Reasonable Efforts***" means the level of effort and resources normally devoted by a Party to conduct a clinical trial for a biopharmaceutical product or compound that is owned by it or to which it has rights, which is of similar market potential, profit potential or strategic value and at a similar stage in its development or product life based on conditions then prevailing.

"***Company***" has the meaning set forth in the preamble to this Agreement.

"***Company Compound(s)***" means BA3011, a Conditional Active Biologic (CAB) Antibody Drug Conjugate (ADC) targeted against tumors positive for the AXL receptor tyrosine kinase, and BA3021, a CAB ADC targeted for Receptor tyrosine kinase-like Orphan Receptor 2 (ROR2) positive tumors.

"***Company Independent Patent Rights***" means any Patent Rights Controlled by the Company (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement that Cover the use (whether alone or in combination with other agents), manufacture, formulation, or composition of matter of either or both of the Company Compounds and/or Biomarker Testing relating to use and administration of Company Compounds.

"***Company Indemnitees***" has the meaning set forth in Section 10.1.

"***Company Regulatory Documentation***" has the meaning set forth in Section 2.1(h).

"***Company Study Data***" has the meaning set forth in Section 7.2.

"***Company Study Invention***" means any Invention to the extent specifically relating to either or both of the Company Compounds (including compositions of matter or formulations of the Company Compounds and methods of use or manufacture of the Company Compounds as a monotherapy) and [***].

"***Company Study Patents***" means any Patent Rights to the extent claiming any Company Study Invention (and not claiming a BMS Study Invention or Combined Therapy Invention).

"***Company Technology***" means all Technology Controlled by the Company (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement related to either or both of the Company Compounds or the Combined Therapy and necessary for the conduct of the Combined Therapy Study. For clarity, Company Technology includes the Technology for Biomarker Testing relating to use and administration of Company Compounds but otherwise does not include (a) Inventions, (b) Study Data or (c) Combined Therapy Study Regulatory Documentation.

"***Compound***" means, as applicable, (a) with respect to BMS, the BMS Compound and (b) with respect to the Company, the Company Compounds.

"***Confidential Information***" has the meaning set forth in Section 8.1.

"***Control***" or "***Controlled***" means, with respect to particular information or intellectual property, that the applicable Party owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

"***Cover***" means, with respect to a valid Patent, that, but for rights granted to a Person under such Patent, the practice by such Person of an invention described in such Patent would infringe a claim included in such Patent, or in the case of a Patent that is a patent application, would infringe a claim in such patent application if it were to issue as a patent. "***Covered***" or "***Covering***" shall have correlative meanings.

"***CRO***" means a contract research organization selected in accordance with Section 2.1(c) by the Sponsoring Party to perform all or part of the activities necessary to conduct a Combined Therapy Study.

"***CRO/Study Site List***" shall have the meaning set forth in Section 2.1(c).

"***Cure Period***" shall have the meaning set forth in Section 11.2(a).

"***Dispute***" shall have the meaning set forth in Section 12.3(a).

"***Effective Date***" has the meaning set forth in the preamble to this Agreement.

"***Executive Officers***" means the Chief Executive Officer of the Company and the Senior Vice President of Oncology Development of BMS, or their respective designees.

"***FDA***" means the United States Food and Drug Administration, or any successor agency having the same or similar authority.

"***GAAP***" means generally accepted accounting principles in the United States.

"***Global Safety Database***" means the database containing Serious Adverse Events, Serious Adverse Drug Reactions and pregnancy reports for the Combined Therapy, which database shall be the authoritative data source for regulatory reporting and responding to regulatory queries.

"***Good Clinical Practices***" or "***GCP***" means, as to the United States and the European Union, applicable good clinical practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, clinical practices equivalent to good clinical practices as then in effect in the United States or the European Union.

"***Good Laboratory Practices***" or "***GLP***" means, as to the United States and the European Union, applicable good laboratory practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, laboratory practices equivalent to good laboratory practices as then in effect in the United States or the European Union.

"***Good Manufacturing Practices***" or "***GMP***" means, as to the United States and the European Union, applicable good manufacturing practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, manufacturing practices equivalent to good manufacturing practices as then in effect in the United States or the European Union.

"***Himalaya Therapeutics SECZ Territory***" means [***]; it being understood and agreed that Company shall be entitled from time to time to notify BMS in writing that one or more of the countries and territories [***] as part of the Territory, and for elimination from the Himalaya Therapeutics SECZ Territory.

"***HIPAA***" means, collectively, the United States Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder, as amended from time to time

"***ICF***" shall have the meaning set forth in Section 2.1(d).

"***IND***" means (a) an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States, (b) a counterpart of such an Investigational New Drug Application that is required in any other country before beginning clinical testing of a

drug in humans in such country, including, for clarity, a "Clinical Trial Application" in the European Union, and (c) all supplements and amendments to any of the foregoing.

"***Indemnify***" shall have the meaning set forth in Section 10.1.

"***Infringement***" shall have the meaning set forth in Section 5.3(a).

"***Initial Study***" shall have the meaning set forth in Section 2.1(a).

"***Initiation***" means the dosing of the first patient in a Combined Therapy Study.

"***Invention***" means any invention made or conceived by or on behalf of a Party, or by or on behalf of the Parties together (including by a Third Party in the performance of the Combined Therapy Study), in the performance of the Combined Therapy Study, Statistical Analysis Plan or Bioanalysis Plan to be conducted under this Agreement.

"***IRB***" means an appropriately constituted group that has been formally designated to review and monitor a Combine Therapy Study that has the authority to approve, disapprove, or require modifications to the Protocol for such Combined Therapy Study.

"***Losses***" shall have the meaning set forth in Section 10.1.

"***Manufacture***" or "***Manufacturing***" means manufacturing, processing, formulating, packaging, labeling, holding (including storage), and quality control testing of a Compound or the Combined Therapy, in each case so as to be suitable for use in the Combined Therapy Study under Applicable Law.

"***Material Safety Issue***" means a Party's good faith belief that there is an unacceptable risk for harm in humans based upon (a) pre-clinical safety data, including data from animal toxicology studies or (b) the observation of serious adverse effects in humans after the Company Compounds or the BMS Compound, either as a single agent or in combination with another pharmaceutical agent (including as the Combined Therapy), has been administered to or taken by humans (including during the Combined Therapy Study).

"***Non-Breaching Party***" shall have the meaning set forth in Section 11.1(a).

"***Non-Prosecuting Party***" shall have the meaning set forth in Section 5.1(c)(ii).

"***Officials***" shall have the meaning set forth in Section 9.9.

"***Ono***" means Ono Pharmaceutical Co. Ltd.

"***Ono-BMS Agreement***" means those certain Collaboration Agreements between BMS and Ono dated as of September 20, 2011 and as of July 23, 2014, as amended from time to time, and agreements between Ono and BMS and their Affiliates relating thereto that may be in effect from time to time.

"***Ono Territory***" means [***].

"***Operational Matters***" shall have the meaning set forth in Section 2.6(c).

"***Other Party***" means, with respect to a Combined Therapy Study, the Party that is not the Sponsoring Party for such Combined Therapy Study.

"***Other Therapy***" means any pharmaceutical compound or therapeutic agent or therapy that is not the Company Compounds or the BMS Compound, where such pharmaceutical compound or therapeutic agent or therapy is specified in the Protocol for a Combined Therapy Study (as may be approved from time to time by both Parties in accordance with Section 2.1), and such Combined Therapy Study and applicable Combined Therapy includes the use of such other therapeutic agent or therapy in combination with the use of the Company Compounds and BMS Compound.

"***Party***" and "***Parties***" have the meaning set forth in the preamble to this Agreement.

"***Patent Rights***" and "***Patent***" means any and all (a) United States or foreign patents, (b) United States or foreign patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon, (c) United States or foreign patents-of-addition, reissues, reexaminations (including without limitation, ex parte reexaminations, inter partes reviews, inter partes reexaminations, post grant reviews and supplemental examinations) and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates, patent term extensions, or the equivalents thereof, and (d) any other form of government-issued right substantially similar to any of the foregoing.

"***Payment***" shall have the meaning set forth in Section 9.9.

"***PD-L1 Expression Testing***" means [***].

"***Person***" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

"***Personal Data***" means any information relating to an identified or identifiable natural person.

"***Pharmacovigilance Agreement***" shall have the meaning set forth in Section 2.2.

"***POTV***" shall have the meaning set forth in Section 8.6.

"***Prosecuting Party***" shall have the meaning set forth in Section 5.1(c).

"***Protocol***" shall have the meaning set forth in Section 2.1(b).

"***Publication Dispute***" shall have the meaning set forth in Section 8.5(b).

"***Quarter***" means a calendar quarter.

"***Regulatory Approval***" shall mean any and all approvals (including supplements, amendments, variations, label expansion, indication extensions, pre- and post-approvals, NDA or BLA approvals, and their foreign equivalents such as MAA approvals), licenses, registrations or authorizations (including marketing and labelling authorizations) of any national, supra-national (e.g., the European Union), regional, state or local Regulatory Authority, department, bureau, commission, council or other governmental entity, that are necessary for the commercial manufacture, commercial use, or sale of a product in a given jurisdiction.

"***Regulatory Authority***" means the FDA or any other governmental authority outside the United States (whether national, federal, provincial and/or local) that is the counterpart to the FDA, including the European Medicines Agency for the European Union.

"***Regulatory Documentation***" means, with respect to the applicable Compound, submissions to Regulatory Authorities in connection with the development of such Compound, including INDs and amendments thereto, applications for Regulatory Approval and amendments thereto, drug master files, correspondence with Regulatory Authorities, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with applicable supporting documents (including documents with respect to clinical data). Definition excludes materials related to the commercial manufacture, commercial use, or sale of a product in a given jurisdiction.

"***Results***" shall have the meaning set forth in Section 8.5(b).

"***Right of Cross-Reference***" means the "right of reference" defined in 21 CFR 314.3(b), including with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a Party's Compound (and, in the case of the Other Party, the Right to Cross-Reference the Combined Therapy IND to the extent expressly permitted by this Agreement), only to the extent necessary for the conduct of the Combined Therapy Study in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder, and, except as to information contained in the Combined Therapy IND pertaining to the Combined Therapy, without the disclosure of information contained in a Party's Regulatory Documentation to the other Party.

"***Samples***" means biological specimens collected from Combined Therapy Study subjects (including fresh and/or archived tumor samples, serum, peripheral blood mononuclear cells, plasma and whole blood for RNA and DNA sample isolation).

"***Safety Information***" means all serious and unexpected suspected adverse reactions (SUSARs), Serious Adverse Events, Serious Adverse Drug Reactions, and other clinically relevant adverse events, safety and toxicity findings, in each case, with respect to a Compound (whether administered alone or in combination with other pharmaceutical agents).

"***Safety Issue***" means any information suggesting an emerging safety concern or possible change in the risk-benefit balance for the Other Party's Compound, including information on a possible causal relationship between an Adverse Event and a drug, the relationship being unknown or incompletely documented previously.

"***Site Agreement***" shall have the meaning set forth in Section 2.1(d).

"***Sponsor-Funded Study***" shall have the meaning set forth in Section 2.1(a).

"***Sponsoring Party***" means, for each Combined Therapy Study, the sponsor of such Combined Therapy Study as the term "sponsor" is defined in 21 CFR. 312.3(b) or any applicable comparable regulation issued by a Regulatory Authority outside the United States. The Sponsoring Party for each such Combined Therapy Study shall be set forth in the Study Plan for such Combined Therapy Study.

"***Statistical Analysis Plan***" means the agreed-upon set of analyses of the Study Data for each Combined Therapy Study conducted hereunder and shall include all analyses of the Combined Therapy in such Combined Therapy Study as specified in the Protocol. The Statistical Analysis Plan shall be set forth in a Statistical Analysis Plan document in accordance with Section 2.1(b).

"***Study***" has the meaning set forth in the definition of Combined Therapy Study.

"***Study Costs***" shall have the meaning set forth in Section 6.2.

"***Study Data***" shall have the meaning set forth in Section 7.1.

"***Study Plan***" means, for each Combined Therapy Study, the plan substantially in the form of Exhibit C that is completed and entered into by the Parties for such Combined Therapy Study as further described in Section 2.1(a).

"***Study Site***" means any of the clinical trial sites used for the Combined Therapy Study.

"***Sunshine Laws***" shall have the meaning set forth in Section 8.6.

"***Supply and Quality Documentation***" shall have the meaning set forth in Section 4.3.

"***Technology***" means information, inventions, discoveries, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance,

designs, drawings, assembly procedures, computer programs, specifications, data and results not generally known to the public (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, whether or not patentable, in written, electronic or any other form now known or hereafter developed, materials, data and results, including Regulatory Documentation.

"***Template Substantive Changes***" means such changes to a document which (a) impose a new obligation, whether direct, indirect or contingent, upon the Other Party, (b) confer a benefit upon Sponsoring Party that is not also conferred upon the Other Party, (c) relate to use of Samples other than for the Biomarker Testing, if any and the PD-L1 Expression Testing, or (d) relate to the information to be disclosed in the ICF or under the Site Agreement regarding the Other Party's Compound.

"***Territory***" means worldwide, excluding the Ono Territory and the Himalaya Therapeutics SECZ Territory.

"***Term***" shall have the meaning set forth in Section 11.1.

"***Third Party***" means any Person or entity other than the Company and BMS and their respective Affiliates.

"***Third Party Claim***" shall have the meaning set forth in Section 10.1.

"***Third Party License Payments***" means any payments (e.g., upfront payments, milestones, royalties) due to any Third Party under license agreements or other written agreements granting rights to intellectual property owned or controlled by such Third Party to the applicable Party, to the extent that such rights are necessary for the making, using or importing of a Party's Compound for the conduct of the Combined Therapy Study or for the conduct of the Combined Therapy Study.

"***Trial Master File***" means the official auditable file of study Essential Documents and Relevant Communications maintained by the Sponsor and its delegates (e.g., Contract Research Organizations (CROs) and vendors) that facilitates the conduct and management of the clinical trial and allows evaluation of the integrity of the study record and compliance with Good Clinical Practice (GCP).

Article 2
Conduct of Combined Therapy Study

2.1 General

(a) **Overview**. BMS and the Company shall collaborate under the terms and conditions of this Agreement to conduct one or more clinical studies of the Combined Therapy in subjects with certain tumor types as described in the applicable Protocol and conducted subject to and in accordance with the terms and conditions of the Agreement (each such clinical study being a "***Combined Therapy Study***" or "***Study***"). As of the Effective Date, and subject to the Parties' agreement on Study Plans with respect to each Combined Therapy Study as described herein, the Parties agree to conduct [***] described in Exhibit A (the "***Initial Studies***"). For each Combined Therapy Study that the Parties desire to conduct under this Agreement, including the Initial Studies, the Parties shall establish and approve in writing a written plan (including a Protocol summary, whether such Combined Therapy Study is a Jointly-Funded Study or to be funded solely by the Sponsoring Party (a "***Sponsor-Funded Study***"), the identity of the Sponsoring Party, the Clinical Obligations Schedule, a draft Bioanalysis Plan, and preliminary CRO/Study Site List for the Combined Therapy Study) in a form substantially similar to that set forth in Exhibit C (each such plan signed by both Parties, a "***Study Plan***," as further described in this Article 2). Each Study Plan shall be sequentially numbered, signed by such person as a Party may authorize, and upon being fully signed shall be incorporated into and made a part of this Agreement and shall be deemed to be included in Exhibit C as an attachment to this Agreement. Each Combined Therapy Study shall be conducted in accordance with the applicable Protocol for such Combined Therapy Study (including any Protocol amendment agreed to by the Parties)

with the Sponsoring Party being solely responsible for overseeing Sponsor-Funded Studies. The Party listed as the Sponsoring Party for a particular activity in a Clinical Obligations Schedule shall be responsible for such activity. For clarity, the Party designated as the Sponsoring Party for obtaining all approvals and clearances (including regulatory and IRB approvals and customs clearances) for the conduct of the applicable Combined Therapy Study shall have the responsibility for doing so. The terms and conditions of this Agreement apply to each Combined Therapy Study conducted pursuant to this Agreement. Accordingly, in each provision of this Agreement where there is reference to "the Combined Therapy Study", such provision shall apply to each and every Combined Therapy Study undertaken by the Parties pursuant to this Agreement. Any changes to the Study Plan shall be made by a written amendment to the Study Plan signed by such person as a Party may authorize.

(b) **Protocol; Statistical Analysis Plan**. Each Combined Therapy Study shall be conducted in accordance with a protocol (including the corresponding protocol synopsis) (the "***Protocol***") to be mutually agreed upon by the Parties. The Study Plan for a Combined Therapy Study shall include an initial summary of the Protocol, and the Protocol shall be based upon such summary. The Parties will also agree prior to the Initiation of the Combined Therapy Study on the statistical analysis section of the Protocol for the Combined Therapy Study. The number of patients to be included in the Combined Therapy Study and Sample requirements will be set forth in the Protocol. The Sponsoring Party shall notify the Other Party of any proposed amendments to the Protocol, including any changes in the dosage or dosage regimen for the BMS Compound, or the Company Compound, amendments that have an impact on patient safety, any changes to the study design, collection of patient samples or indications to be explored, and shall consider and discuss in good faith all comments, and suggestions provided by the Other Party before initiating any such amendment. The Statistical Analysis Plan document for the Combined Therapy Study will be agreed to by the Parties upon finalization of the template CRF. Any amendment to the Protocol or the Statistical Analysis Plan must be agreed to in writing by both Parties.

(c) **Study Site and CRO Selection**. The Study Sites, CROs and other contractors or vendors that may be used by the Sponsoring Party to conduct the Combined Therapy Study shall be selected by the Sponsoring Party from the list of such Study Sites, CROs and other contractors and vendors as agreed to by the Parties in advance as set forth in this Section 2.1(c) (such list being the "***CRO/Study Site List***"). The Study Plan for a Combined Therapy Study shall include a preliminary CRO/Study Site List for the applicable Combined Therapy Study. The Sponsoring Party may modify the CRO/Study Site List during the Combined Therapy Study; provided, however, that any changes to the CRO/Study Site List for a Jointly-Funded Study will require [***]. The Sponsoring Party shall have the authority to select the final Study Sites, CROs and contractor/vendors from the CRO/Study Site List based on its feasibility analysis, provided that the CRO/Study Site List shall only include study sites located in the territories listed on Schedule 2.1(c).

(d) **ICF, Case Report Forms and Site Agreement Templates**. BMS and the Company will create agreed upon templates for the informed consent form ("***ICF***"), the case report form ("**CRF**"), and the Study Site agreement ("***Site Agreement***") for each Combined Therapy Study. The Sponsoring Party shall have the authority to modify the template ICF, the template CRF and template Site Agreement based on its negotiations with Study Sites unless such modification includes a Template Substantive Changes, in which case written approval by the Other Party[***], shall be required. Notwithstanding any modification of the ICF, the Sponsoring Party shall ensure that in all cases the ICF includes: (i) disclosure of the risks and discomforts associated with Compounds of the Other Party that is substantially similar to those identified in the safety information made available by the Other Party, and (ii) consent from the Combined Therapy Study patients to collect and use the Samples for research and development of the BMS Compound, the Company Compound and the Combined Therapy, and to perform Biomarker Testing and PD-L1 Expression Testing, and (iii) that the patient waives any rights he or she may have to such Samples after collection.

(e) **CRO Agreements**. The Sponsoring Party will be responsible for drafting, negotiating and entering into agreements and any amendments thereto with any CROs used for the conduct of a Combined Therapy Study (each being a "***CRO Agreement***"). The Sponsoring Party shall provide the Other Party with a copy of each executed CRO Agreement and any amendments thereto. Except as the Parties otherwise agree in writing, each CRO Agreement:

(i) shall be subordinate to and consistent with the terms and conditions of this Agreement, and shall not limit the Sponsoring Party's ability to fully perform all of its obligations under this Agreement or the Other Party's rights under this Agreement (including the Other Party's rights with respect to the Study Data and Patents claiming Inventions from the work conducted by the CRO under the CRO Agreement);

(ii) shall not adversely affect the Technology or Compound of the Other Party (i.e., the BMS Technology or BMS Compound, or as the case may be, the Company Technology or Company Compound) or impose a new obligation, whether direct, indirect or contingent, upon the Other Party;

(iii) shall not limit the Other Party's rights with respect to the use of Samples in accordance with the applicable approved ICFs;

(iv) and (iv) shall not confer a benefit upon the Sponsoring Party that is not also conferred upon the Other Party.

(f) **IND**. The Sponsoring Party (as specified in the Study Plan for each Combined Therapy Study) shall hold the IND for such Combined Therapy Study. Each Combined Therapy Study shall be conducted under either an existing BMS IND or Company IND as set forth in the Study Plan or, if required by Regulatory Authorities, a new combination IND (such combination IND being the "***Combined Therapy IND***"). For the avoidance of doubt, each Party shall be responsible for (i) drafting and updating, as necessary, the investigator's brochure for its respective Compound (or in the case where a new Combined Therapy investigator's brochure is required, the Parties shall be jointly responsible for drafting and updating such Combined Therapy investigator's brochure as necessary), and (ii) filing all necessary Regulatory Documentation to the existing IND for its respective Compound, including, but not limited to, the submission to such existing IND of serious adverse event and adverse drug reaction cases emerging from the Combined Therapy Study.

(g) **Safety Evaluation**. Each Party shall provide the following information with respect to its Compound to be used in a Combined Therapy Study: (i) the latest investigator's brochure and annual updates (with such updates to be provided within five (5) Business Days after being finalized), (ii) list of ongoing clinical studies, (iii) Aggregate Safety Information that emerge from all other clinical trials of the Party's Compound within five (5) Business Days after general distribution within such Party, (iv) prompt notice of any material safety interactions with any Regulatory Authority and the substance thereof regarding any clinical trials of the Party's Compound during the term of this Agreement; (v) a summary of all new clinically relevant toxicology study data on the Party's Compound within five (5) Business Days after generation of such summary within such Party, (vi) safety analyses for the Combined Therapy Study in accordance with the applicable Statistical Analysis Plan, and (vii) such other safety data as set forth in the Pharmacovigilance Agreement. Except as permitted under Section 8.3(g) and Section 8.4, each Party shall use any such information provided by the other Party pursuant to this Section 2.1(g) solely to evaluate the safety of the Combined Therapy and the Compounds for use in the Combined Therapy Study.

(h) **Regulatory Documentation**. The Other Party shall jointly review, and provide comments to the Sponsoring Party within five (5) Business Days on all substantive Combined Therapy Study Regulatory Documentation and provide the Sponsoring Party with copies of Regulatory Documentation relating to its own Compound and Technology ("***Company Regulatory Documentation***" in the case that Company is the Other Party, and "***BMS Regulatory Documentation***" in the case that BMS is the Other Party), in each case as both Parties agree is necessary or reasonably expected to be necessary, and is requested by the Sponsoring Party, (i) to obtain and maintain the IND for the Combined Therapy Study and prepare and file any Combined Therapy Study Regulatory Documentation in accordance with this Agreement, or (ii) to comply with Applicable Law with regard to the Other Party's Compound, and the Combined Therapy Study, which may include information regarding the pharmacokinetics, efficacy and safety of the Other Party's Compound alone or in combination with the Sponsoring Party's Compound.

(i) **Right of Cross-Reference**. Each Party shall provide a Right of Cross-Reference to its existing Regulatory Documentation for its Compound to the extent necessary for the conduct of each particular Combined Therapy Study, *provided* that, except as provided in Section 3.1 and Section 3.2, such Right of

Cross-Reference shall terminate upon the earlier of the completion or termination of such Combined Therapy Study, and the expiration or termination of this Agreement. If a Combined Therapy Study is terminated for a Material Safety Issue pursuant to Section 11.3, such Right of Cross-Reference shall remain in effect solely to the extent necessary to permit the Company to comply with any outstanding obligations required by a Regulatory Authority or Applicable Law, or as necessary to permit the Sponsoring Party to continue to dose subjects enrolled in the Combined Therapy Study through completion of the Protocol if required by the applicable Regulatory Authority(ies) and/or Applicable Laws.

(j) **Collaboration Management**. Each Party will appoint appropriate staff to act as its Designated Clinical Contact (each, a "***Designated Clinical Contact***"). The role of the Designated Clinical Contacts is to act as the primary points of contact between the Parties to assure a successful relationship between the Parties. Each Party may change its Designated Clinical Contact from time to time upon written notice to the other Party. Any Designated Clinical Contact may designate a substitute to temporarily perform the functions of such Designated Clinical Contact upon written notice to the other Party's Designated Clinical Contact. Each Designated Clinical Contact will be charged with creating and maintaining a collaborative work environment. Each Designated Clinical Contact also will:

(i) provide a point of communication both internally within the Parties' organizations and between the Parties regarding the Sponsor-Funded Study, including receiving Study Data, and quarterly updates from the Sponsoring Party;

(ii) coordinate review, and approval if required, of documents to be used for the Jointly-Funded Study and for which agreement of both Parties is required, including the Protocol, the Statistical Analysis Plan, the template ICF, the template CRF, and the template Site Agreement;

(iii) coordinate the negotiation and execution of additional agreements between the Parties, as required under this Agreement, including the Pharmacovigilance Agreement, the Supply and Quality Documentation, and the Good Clinical Practice Quality Agreement;

(iv) coordinate the disclosure, review, and comments related to Regulatory Documentation disclosed between the Parties; and communications with Regulatory Authorities as provided herein;

(v) coordinate the initial disclosure, reporting, and updating of all safety information related to the respective Compounds of each Party, and the Combined Therapy Study, provided that any information disclosed pursuant to the Pharmacovigilance Agreement shall be handled according to the provisions thereof.

2.2 Adverse Event Reporting; Safety Data Exchange. The Parties shall use diligent efforts to define and finalize the processes the Parties shall employ to protect patients and promote their well-being in connection with the use of the Combined Therapy, and to execute a written pharmacovigilance agreement (the "***Pharmacovigilance Agreement***") within ninety (90) days of the Effective Date, and provided that in all cases the Pharmacovigilance Agreement shall be executed by the Parties prior to the first dosing of the first study patient in any new clinical trial subject to this Agreement. Such Pharmacovigilance Agreement shall (a) provide that the Company shall hold and be responsible for the maintenance of the Global Safety Database for the Company Compounds and that BMS shall hold and be responsible for the maintenance of the Global Safety Database for the BMS Compound, (b) provide that the Sponsoring Party for the applicable Combined Therapy Study shall be responsible for the safety reporting for the applicable Combined Therapy and shall lead all pharmacovigilance activities for the applicable Combined Therapy and (c) include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety of the Combined Therapy. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to government authorities. Furthermore, such agreed procedures shall be consistent with relevant International Council for Harmonization (ICH) guidelines, except where said guidelines may conflict with existing local regulatory safety reporting requirements or Applicable Law, in which case local

reporting requirements or Applicable Law shall prevail. In the event of a conflict between the terms this Agreement and the terms of the Pharmacovigilance Agreement, the Pharmacovigilance Agreement shall control to the extent related to pharmacovigilance matters associated with the Combined Therapy Study and the terms of this Agreement control with respect to any other matters. In the event that this Agreement is terminated, the Parties agree to implement the necessary procedures and practices to ensure that any outstanding pharmacovigilance reporting obligations are fulfilled.

BMS – Adverse Event Reporting Contact	
E-mail:	Worldwide.safety@bms.com
Fax:	+1 609 818-3804

2.3 Good Clinical Practice Quality Agreement. If the Parties deem necessary, the Parties shall use diligent efforts to define and finalize clinical quality processes, and to execute a written good clinical practice quality agreement (the "**Good Clinical Practice Quality Agreement**") within ninety (90) days after the Effective Date, but in any event prior to the date of the first dosing of the Other Party's Compound for use in the Combined Therapy Study. The Good Clinical Practice Quality Agreement shall define between the Parties clinical auditing responsibilities, audit activity information sharing, escalation of quality issues and interaction and responsibilities during Regulatory Authority inspection.

2.4 Specific Responsibilities of the Sponsoring Party. The Sponsoring Party for a particular Combined Therapy Study shall be responsible (with respect to such Combined Therapy Study) for:

(a) drafting the Protocols and Statistical Analysis Plans, and any amendments to each of the foregoing, in consultation with the Other Party, and having primary responsibility for conduct of the Combined Therapy Study and the analysis of the Study Data under the applicable Statistical Analysis Plan. In consultation with the Other Party, in accordance with the terms and conditions of this Agreement;

(b) negotiating, entering into, and managing contracts for services related to the Combined Therapy Study, including Site Agreements, obtaining IRB approval for site ICFs, obtaining signed ICFs and monitoring plans, and ensuring that any such contracts allow the Other Party to exercise all rights granted under this Agreement, including access to and use of Study Data, and other information and documents (and in no event not less than the same access or use rights as is granted to the Sponsoring Party);

(c) providing the Other Party, according to the schedule established in the Supply and Quality Documentation, a clinical drug supply forecast for the BMS Compound and the Company Compound that includes strategy for drug supply overages, drug supply quantity and required delivery dates;

(d) with the cooperation of the Other Party, compiling, amending and filing all necessary Combined Therapy Study Regulatory Documentation with Regulatory Authority(ies); maintaining and acting as the sponsor of record as provided in 21 CFR 312.50 (and applicable comparable regulation issued by a Regulatory Authority outside the United States) with responsibility, subject to delegation to a CRO in accordance with 21 CFR 312.52 (and applicable comparable or any applicable comparable regulation issued by a Regulatory Authority outside the United States), for the Combined Therapy Study; and making all required submissions to Regulatory Authorities related thereto on a timely basis;

(e) with the cooperation of the Other Party, and subject to the provisions of Section 8.5, listing the Combined Therapy Study trials required to be listed on a public database on www.clinicaltrials.gov or other public registry in any country in which such Combined Therapy Study is being conducted in accordance with Applicable Law and in accordance with each Party's internal policies relating to clinical trial registration;

(f) providing the Other Party with reasonable advance notice of scheduled meetings or other substantive out-going or pre-planned non-written communications with a Regulatory Authority and the opportunity

to participate in each such meeting or other non-written communication, to the extent that it relates to the Other Party's Compound (i.e., the Company Compound or BMS Compound, as the case may be), and providing the Other Party with the opportunity to review, provide comments to the Sponsoring Party within five (5) Business Days, and, if inconsistent with the Protocol, approve all substantive submissions and written correspondence with a Regulatory Authority that relates to the Other Party's Compound; *provided* that in no event shall the Sponsoring Party or any Affiliate of the Sponsoring Party communicate with any Regulatory Authority solely with respect to the Other Party's Compound without the prior written consent of the Other Party and *provided further* that the Other Party shall step out of any portions of such meetings or other non-written communications with a Regulatory Authority that relate solely to the Sponsoring Party's Compound (i.e., the Company Compound or BMS Compound, as the case may be) and the Sponsoring Party shall step out of any portions of such meetings or other non-written communications with a Regulatory Authority that relate solely to the Other Party's Compound;

(g) providing to the Other Party a written summary of meetings or other substantive non-written communications with a Regulatory Authority within ten (10) Business Days of such meeting or communication, and copies of any official correspondence to or from a Regulatory Authority within three (3) Business Days of receipt or provision, in each case to the extent that it relates to the Other Party's Compound (or, to the extent the communication would adversely impact the performance of the Combined Therapy Study, the Sponsoring Party's Compound), and copies of all Combined Therapy Study Regulatory Documentation that relate to the Combined Therapy or the Other Party's Compound within five (5) Business Days of submission to Regulatory Authorities;

(h) drafting, and providing to the Other Party for its review, the Protocol, in the event that a new Combined Therapy investigator's brochure is required by a Regulatory Authority for the Combined Therapy Study, the investigator's brochure for the Combined Therapy Study, template ICF, template CRF and Statistical Analysis Plan, and any amendments to each of the foregoing;

(i) coordinating with the Other Party, and providing, 10 days in advance of submission, drafts of submissions to the Combined Therapy IND (with the reporting of Safety Information being subject to the Pharmacovigilance Agreement) (if applicable), and Combined Therapy Study Regulatory Documentation, or portions thereof, that relate to the Other Party's Compound, and providing the Other Party with the opportunity to review, comment on and (if inconsistent with the Protocol) approve all other substantive written correspondence with a Regulatory Authority relating to the Combined Therapy Study, to the extent such correspondence relates to the Other Party's Compound, *provided* that the Other Party shall provide any such comments within five (5) Business Days, and in the event that a Regulatory Authority requests a shorter timeframe for response than outlined herein, the Parties will use all reasonable efforts to meet the deadline;

(j) managing the operations of the Combined Therapy Study in accordance with the Protocol, including overseeing compliance by any CRO with the terms of the applicable CRO Agreement relating to the Combined Therapy Study;

(k) providing to the Other Party a list of all proposed clinical trial sites and principal investigator(s) for the Combined Therapy Study for the Other Party's review and comment, and take into account the Other Party's experience and comments with regard to sites that have previously conducted studies with the Other Party's Compound;

(l) ensuring that all Site Agreements and CRO Agreements comply with Section 2.1(d) and Section 2.1(e), respectively, and (A) contain intellectual property provisions that retain each of the Parties' respective intellectual property rights in the Company Compound, BMS Compound and Combined Therapy, and (B) allow for the Other Party, as well as the Sponsoring Party, to the extent permitted by Applicable Law, and any Third Party confidentiality restrictions or obligations, to audit the Study Sites for quality assurance, and to inspect and copy all data, documentation and work products relating to the activities performed by the Study Site, including the medical records of any patient participating in the Combined Therapy Study (where such right to inspect and copy all data, documentation and work products of a Study Site shall survive the termination or expiration of the applicable CRO Agreement or Site Agreement);

(m) providing the Other Party with access to the Trial Master File for the for the Combined Therapy Study;

(n) providing the Other Party with: (i) an opportunity to participate in discussions with any and all external drug safety monitoring boards for the Combined Therapy Study, (ii) an opportunity to review and comment on minutes from any and all external drug safety monitoring boards for the Combined Therapy Study prior to their submission, and (iii) a copy of all final minutes from any and all external drug safety monitoring boards for the Combined Therapy Study within five (5) Business Days after receipt by the Sponsoring Party;

(o) providing the Other Party with updates on the status of the Combined Therapy Study at the Other Party's reasonable request, including but not limited to information regarding the number and status of study sites, the number of screened subjects (actual to target), the number of randomized subjects (actual to target), the number of dosed, ongoing, discontinued and completed subjects, and any safety updates as contemplated by the Protocol, Section 2.1(d), or routinely performed by a Party in its normal course of trial management and reporting;

(p) subject to the provisions of Section 2.2, and the Pharmacovigilance Agreement:

(i) owning and maintaining the Global Safety Database, and being responsible for safety reporting to Regulatory Authorities for the Combined Therapy;

(ii) collecting, evaluating and reporting serious adverse events, other Safety Information and any further pharmacovigilance information from the Combined Therapy Study;

(iii) sending any communications (including investigator notification letters) to Study Sites (including IRBs) regarding Safety Information for the Combined Therapy Study

(iv) on a semi-annual basis, providing tables, figures, and listings of the aggregated data related to the safety of the Other Party's Compound, as determined by the relevant treating clinical investigator(s), and generated by the Sponsoring Party in its updates of the investigator's brochure; and

(v) providing the Other Party with the opportunity to participate in and comment on such pharmacovigilance activities;

(q) analyzing the Study Data in a timely fashion, and providing the Other Party with access to the Study Data from the applicable Combined Therapy Study as follows:

(i) pursuant to a timetable determined by the Parties, sharing with the Other Party (1) all drafts of any interim report, clinical study report and statistical analysis (in accordance with the Statistical Analysis Plan) from the Combined Therapy Study for review and comment, (2) any final interim report, final clinical study report and final statistical analysis (in accordance with the Statistical Analysis Plan) from the Combined Therapy Study, (3) biomarker analysis data sets (vendor reports or internal analysis reports), such as exploratory measures from exploratory analysis, and (4) the raw Study Data in electronic or other mutually agreed format (with each Party having the right to review any analyses conducted on the Study Data by the other Party for consistency with its analyses);

(ii) provide to the Other Party within thirty (30) Business Days after database lock, a copy of the statistical output data described in the Statistical Analysis Plan in the clinical trial databases that will be used for an interim review by an external consultant (or drug safety monitoring board, if required), with such consultant and the timing for such interim review to be agreed upon by the Parties;

(iii) within ten (10) Business Days after database lock, a copy of all Safety Information that will be used for an interim review by an external consultant (or drug safety monitoring board, if required), with such consultant and the timing for such interim review to be agreed upon by the Parties;

(iv) within ten (10) Business Days after database lock, access to final CRFs or patient profiles for all patients in the Combined Therapy Study;

(v) periodically during the conduct of the Combined Therapy Study (and within thirty (30) calendar days after the creation of a clean database), copies of the Form 1572s, financial disclosures and other relevant documents required to meet regulatory requirements related to the Combined Therapy Study (including without limitation any data or documents that may be required to provide Aggregate Safety Information to a Regulatory Authority with respect to the Other Party's Compound); and

(vi) subject to Articles 7 and 8 and any third party requirements, providing the Other Party with any SAS codes to be used for the Statistical Analysis Plan for the Combined Therapy Study.

2.5 Operational Authority of Sponsoring Party Generally. The Sponsoring Party, as designated in the Clinical Obligations Schedule of the Study Plan for each Combined Therapy Study, shall, subject to the terms of the Protocol, and the terms and conditions of this Agreement:

(a) manage and be primarily responsible for conducting the Combined Therapy Study;

(b) be responsible for regulatory interactions with respect to the Combined Therapy Study; and

(c) be responsible for the following matters with respect to the Combined Therapy Study ("***Operational Matters***"):

(i) the selection and management of the Study Sites from the CRO/Study Site List (including budget negotiations with vendors, timelines and contingency planning);

(ii) conducting clinical study start-up activities (including engaging the CRO(s), communicating with and obtaining approval from IRB(s), and/or ethics committees, as applicable, and drafting the template ICF and CRF for the Combined Therapy Study);

(iii) subject recruitment and retention activities;

(iv) ongoing site monitoring and quality assurance audits;

(v) subject to the terms of the Pharmacovigilance Agreement, management of safety reporting by contract research organizations and clinical Study Sites;

(vi) ongoing medical monitoring;

(vii) management, monitoring and audits of CRO(s) in connection with each CRO Agreement , and

(viii) inquiries from clinical study subjects.

(d) The Sponsoring Party of a Combined Therapy Study, shall provide the Other Party with access to the Study Data in accordance with the terms and conditions of this Agreement, and shall provide monthly updates regarding the progress of the Combined Therapy Study to the Other Party.

2.7 Other Clinical Trials. Nothing in this Agreement shall preclude either Party from conducting any other clinical trials as it may determine in its discretion, so long as it does not use or rely on the Confidential Information that is solely owned by the other Party in doing so.

2.8 Subsequent Studies. The Parties shall sign the Study Plan for the Initial Study concurrently with the execution of this Agreement. Should additional clinical studies to evaluate the combination of either of the Company Compounds with the BMS Compound ("**Subsequent Studies**") be of interest to either Party during the term, the Parties will discuss such studies in good faith. If a Subsequent Study is of mutual interest to both Parties,

such Subsequent Study collaboration would be subject to a new Study Plan that is agreed to and executed by both Parties.

Article 3
License Grants

3.1 Grants by BMS

(a) BMS hereby grants, and shall cause its Affiliates to grant, to the Company and the Company's Affiliates a non-exclusive, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) in the Territory under the BMS Independent Patent Rights, BMS Technology and BMS Regulatory Documentation to use the BMS Compound in research and development, solely to the extent necessary to conduct the Combined Therapy Study subject to and in accordance with the terms and conditions of this Agreement.

(b) BMS hereby grants, and shall cause its Affiliates to grant, to the Company and the Company's Affiliates a non-exclusive, non-transferable, irrevocable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) in the Territory under the BMS Independent Patent Rights, BMS Technology and BMS Regulatory Documentation to seek Regulatory Approval of the Company Compounds solely for use in a Combined Therapy, and, upon any receiving such Regulatory Approval, to market and promote the Company Compounds solely for use in a Combined Therapy in any manner that is consistent with the Regulatory Approval for the Company Compounds. The right granted under this Section 3.1(b) includes a Right of Cross-Reference to the relevant BMS Regulatory Documentation solely to the extent necessary and solely for the purpose of obtaining Regulatory Approval in the Territory for the Company Compounds solely for use in a Combined Therapy based upon a Combined Therapy Study (which right shall survive any expiration or termination of this Agreement). In such case, BMS shall reasonably cooperate with the Company and make written authorizations and other filings with the applicable Regulatory Authority reasonably required to effect such Right of Cross-Reference. For avoidance of doubt, no rights are granted under this Section 3.1(b) for the Ono Territory or Himalaya Therapeutics SECZ Territory and no rights are granted except for use in a Combined Therapy (i.e., use of the Company Compounds in combination with the BMS Compound), with no rights being granted for the use of any other pharmaceutical compound or therapeutic agent other than the Company Compound in combination with the BMS Compound.

3.2 Grants by the Company

(a) The Company hereby grants, and shall cause its Affiliates to grant, to BMS and BMS' Affiliates a non-exclusive, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) in the Territory under the Company Independent Patent Rights, Company Technology and Company Regulatory Documentation to use the Company Compounds in research and development, solely to the extent necessary to conduct the Combined Therapy Study subject to and in accordance with the terms and conditions of this Agreement.

(b) The Company hereby grants, and shall cause its Affiliates to grant, to BMS and BMS' Affiliates a non-exclusive, non-transferrable, irrevocable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) in the Territory under the Company Independent Patent Rights, Company Technology and Company Regulatory Documentation to seek Regulatory Approval of the BMS Compound solely for use in a Combined Therapy, and, upon receiving any such Regulatory Approval, to market and promote the BMS Compound solely for use in a Combined Therapy in any manner that is consistent with the Regulatory Approval for the BMS Compound. The right granted under this Section 3.2(b) includes a Right of Cross-Reference to the relevant Company Regulatory Documentation solely to the extent necessary and solely for the purpose of obtaining Regulatory Approval in the Territory for the BMS Compound

solely for use in a Combined Therapy based upon a Combined Therapy Study (which right shall survive any expiration or termination of this Agreement). In such case, the Company shall reasonably cooperate with BMS and make written authorizations and other filings with the applicable Regulatory Authority reasonably required to effect such Right of Cross-Reference. For avoidance of doubt, no rights are granted under this Section 3.2(b) for the Ono Territory or Himalaya Therapeutics SECZ Territory and no rights are granted except for use in a Combined Therapy (i.e., use of the BMS Compound in combination with either of the Company Compound), with no rights being granted for the use of any other pharmaceutical compound or therapeutic agent other than the BMS Compound in combination with the Company Compounds.

3.3 Sublicensing

(a) Each Party shall have the right to grant sublicenses under the licenses granted to it under Section 3.1(a) in the case of the Company, or under Section 3.2(a) in the case of BMS, to their respective Affiliates and, if required for a Third Party to perform its duties (to the extent permitted under the terms and conditions of this Agreement), to Third Parties, solely as necessary to assist the sublicensing Party in carrying out its responsibilities with respect to the Combined Therapy Study. Each Party shall have the right to grant sublicenses under the licenses granted to it under Section 3.1(b) in the case of the Company, or under Section 3.2(b) in the case of BMS, to their respective Affiliates and Bona Fide Collaborators. For the avoidance of doubt neither BMS nor any of its Affiliates or sublicensees will have the right to grant Ono any sublicenses, within the Ono Territory, under the licenses granted to it under Section 3.2.

(b) With regard to any such sublicenses permitted and made under this Agreement, (i) such sublicensees, except Affiliates (so long as they remain Affiliates of a Party), shall be subject to written agreements that bind such sublicensees to obligations that are consistent with a Party's obligations under this Agreement including, but not limited to, confidentiality and non-use provisions similar to those set forth in this Agreement, and provisions regarding intellectual property that ensure that the Parties will have the rights provided under this Agreement to any intellectual property created by such sublicensee, (ii) each Party shall provide written notice to the other of any such sublicense prior to its execution and shall consider any comments provided by the other Party, and (iii) the licensing Party shall remain liable for all actions of its sublicensees.

3.4 Rights for Combined Therapy Patents. The rights of the Parties with respect to the Combined Therapy Inventions and Combined Therapy Patents are set forth in Section 5.1(c).

3.5 Use of Study Data and Samples. The rights of the Parties with respect to the use and disclosure of the Study Data and the use of Samples are set forth in Article 7.

3.6 No Implied Licenses. Except as specifically set forth in this Agreement, neither Party shall acquire, by implication or otherwise, any license or other intellectual property interest in any intellectual property of the other Party, including Confidential Information disclosed to it under this Agreement, or under any Patent Rights Controlled by the other Party or its Affiliates. Except for the licenses granted by BMS under Section 3.1, or by the Company under Section 3.2, nothing in the Agreement is intended or shall be construed as granting either Party any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale or import the other Party's Compound.

3.7 Notification. During the period beginning on the Effective Date and ending one hundred eighty (180) days after the date on which the Company provides BMS with the final clinical study report and final statistical analysis (in accordance with the Statistical Analysis Plan) for the Initial Study, [***] notify BMS in writing of the proposed transaction under subsections (a) or (b) of this Section 3.7, including the geographic territory (but excluding the identity of any bidder or any financial provisions proposed) to be covered in the proposed transaction.

Article 4
Manufacture and Supply of Compounds

4.1 Company Compounds

(a) **Manufacture and Supply**. The Company shall Manufacture or have Manufactured the Company Compounds and shall supply, or cause to be supplied, the Company Compounds for the conduct of the Combined Therapy Study. The cost of Manufacture and supply of Company Compounds for the Combined Therapy Studies shall be borne solely by the Company. The Company shall bear the risk of loss for the Company Compounds, except that in the case where BMS is the Sponsoring Party, the Company shall bear the risk of loss for the Company Compounds to BMS, or its designee until delivery in accordance with the delivery terms set forth in the applicable Supply and Quality Documentation, and risk of loss for such Company Compounds shall then transfer from the Company to BMS upon such delivery. The Company Compounds shall be Manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the Company Compounds used by the Company for its other clinical trials of the Company Compounds. The Company shall deliver to BMS certificates of analysis, and any other documents specified in the Supply and Quality Documentation, including such documentation as is necessary to allow BMS to compare the certificate of analysis for the Company Compounds to the specifications for the Company Compounds. The Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) relating to the Company Compounds in connection with this Agreement, *provided* that in any event the Company may utilize its established supply chain for the supply of Company Compounds.

(b) **Use of Company Compound Supplied by the Company to BMS**. BMS shall use the Company Compounds supplied to it (i.e., in the case where BMS is the Sponsoring Party for the applicable Combined Therapy Study) solely as necessary for, and in accordance with, this Agreement and the Protocols, and for no other purpose, including without limitation as a reagent or tool to facilitate its internal research efforts, for any commercial purpose, or for other research unrelated to the Combined Therapy Study. For avoidance of doubt, the Company Compounds provided by the Company under this Agreement shall not be used by or on behalf of BMS or its Affiliates in the Ono Territory. Except as may be required under this Agreement or the Protocol, BMS shall not perform, and shall not allow any Third Parties to perform, any analytical testing of the Company Compounds.

4.2 BMS Compound

(a) **Manufacture and Supply**. BMS shall Manufacture or have Manufactured the BMS Compound and supply, or cause to be supplied, the BMS Compound for the conduct of the Combined Therapy Study. The cost of Manufacture and supply of the BMS Compound shall be borne solely by BMS. BMS shall bear the risk of loss for the BMS Compound, except that in the case where the Company is the Sponsoring Party, BMS shall bear the risk of loss for the BMS Compound until delivery to the Company, or its designee, in accordance with the delivery terms set forth in the applicable Supply and Quality Documentation, and risk of loss for such BMS Compound shall then transfer from BMS to the Company upon such delivery. The BMS Compound shall be Manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the BMS Compound used by BMS for its other clinical trials of the BMS Compound. BMS shall deliver to the Company certificates of analysis, and any other documents specified in the Supply and Quality Documentation, including such documentation as is necessary to allow the Company to compare the BMS Compound certificate of analysis to the BMS Compound specifications. The Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) relating to the BMS Compound in connection with this Agreement, *provided* that in any event BMS may utilize its established supply chain for the supply of BMS Compound.

(b) **Use of BMS Compound Supplied by BMS to the Company**. The Company shall use the BMS Compound supplied to it (i.e., in the case where the Company is the Sponsoring Party for the applicable Combined Therapy Study) solely as necessary for, and in accordance with, this Agreement and the Protocols, and for no other purpose, including without limitation as a reagent or tool to facilitate its internal research efforts, for

any commercial purpose, or for other research unrelated to the Combined Therapy Study. For avoidance of doubt, the BMS Compound provided by BMS under this Agreement shall not be used by or on behalf of the Company or its Affiliates in the Ono Territory. Except as may be required under this Agreement or the Protocol, the Company shall not perform, and shall not allow any Third Parties to perform, any analytical testing of the BMS Compound.

4.3 Supply and Quality Documentation. The Other Party shall supply its Compound to the Sponsoring Party in accordance with such supply and quality addenda or agreement(s) as the Parties may agree (the "***Supply and Quality Documentation***"). The Parties shall finalize and execute the Supply and Quality Documentation in no event later than the date on which the first shipment of the Other Party's Compound is supplied for use in the Combined Therapy Study. The Supply and Quality Documentation shall outline the additional roles and responsibilities relative to the quality of each Party's Compound in support of the Combined Therapy Study. It shall include the responsibility for quality elements as well as exchanged GMP documents and certifications required to release the Other Party's Compound for the Combined Therapy Study. In addition, the Supply and Quality Documentation shall detail the documentation required for each shipment of the Other Party's Compound supplied.

4.4 Customs Valuation. The Sponsoring Party will provide the Other Party in writing with a list of all countries in which Study Sites conducting a particular Combined Therapy Study are located (with such Study Sites being selected from the CRO/Study Site List for such Combined Therapy Study) prior to start of such Combined Therapy Study. During the conduct of such Combined Therapy Study, the Sponsoring Party will send in writing any changes to the list of Study Site countries to the Other Party one month prior to the end of each Quarter. If no changes are sent to the Other Party by the Sponsoring Party for a particular Quarter, the prior Quarter's Study Site country list will be used as the basis for customs valuation for that Quarter. The Other Party will provide the Sponsoring Party with its applicable Compound country-specific customs valuations initially prior to start of the applicable Combined Therapy Study. The expiration date(s) of the customs value(s) will be monitored by the Sponsoring Party and the Sponsoring Party will send a request in writing to the Other Party to provide updated customs value(s) and expiration date(s) at least thirty (30) days in advance of any customs value expirations. The Sponsoring Party will use the country-specific customs valuations for the Other Party Compound as provided by the Other Party, for purposes of the import/export process for the Compound to the applicable Study Site countries and not make any change to such valuations without the Other Party's prior written consent.

Article 5
Patent Prosecution and Enforcement

5.1 Ownership of Inventions and Patent Rights

(a) **Company Study Inventions and Company Study Patents**. All Company Study Inventions and Company Study Patents shall be owned solely by the Company, and the Company will have the full right to exploit such Company Study Inventions and Company Study Patents without the consent of, or any obligation to account to, BMS, subject to the terms and conditions of this Agreement. BMS shall assign and hereby assigns all right, title and interest in any Company Study Inventions and Company Study Patents to the Company. Any assignments necessary to accomplish the foregoing are hereby made, and BMS shall execute such further documents and provide other assistance as may be reasonably requested by the Company to perfect the Company's rights in such Company Study Inventions and Company Study Patents, all at the Company's expense. The Company shall have the right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues,

reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any Company Study Patents at its own expense.

(b) **BMS Study Inventions and BMS Study Patents**. All BMS Study Inventions and BMS Study Patents shall be owned solely by BMS, and BMS will have the full right to exploit such BMS Study Inventions and BMS Study Patents without the consent of, or any obligation to account to, the Company, subject to the terms and conditions of this Agreement. The Company shall assign and hereby assigns all right, title and interest in any BMS Study Inventions and BMS Study Patents to BMS. Any assignments necessary to accomplish the foregoing are hereby made, and the Company shall execute such further documents and provide other assistance as may be reasonably requested by BMS to perfect BMS' rights in such BMS Study Inventions and BMS Study Patents, all at BMS' expense. BMS shall have the right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any BMS Study Patents at its own expense.

(c) **Combined Therapy Inventions and Combined Therapy Patents**

(i) All Combined Therapy Study Inventions and Combined Therapy Patents shall be jointly owned by the Parties according to the laws of the United States, and either Party shall have the right to freely exploit and practice all rights under the Combined Therapy Inventions and Combined Therapy Patents without benefit, accounting or obligation to, or consent required from, the other Party, *provided* that such right shall be subject to the restrictions on disclosure of Combined Therapy Study Data as set forth in Articles 7 and 8.

(ii) The Parties shall determine which Party, using outside counsel acceptable to both Parties, shall be responsible for preparing and prosecuting Patent applications and maintaining Patents that are Combined Therapy Patents. The Party drafting and prosecuting any Combined Therapy Patent (the "***Prosecuting Party***") shall keep the other Party (the "***Non-Prosecuting Party***") advised as to all material developments and all steps to be taken with respect thereto, and shall furnish the Non-Prosecuting Party with copies of applications for such Patents, amendments thereto and other related correspondence to and from Patent offices, and permit the Non-Prosecuting Party a reasonable opportunity to review and offer comments. The Non-Prosecuting Party shall reasonably assist and cooperate in obtaining, prosecuting and maintaining the Combined Therapy Patents. Notwithstanding the foregoing, the Prosecuting Party shall not take any position in a submission to a Patent office that interprets the scope of a Patent or Patent application of the Non-Prosecuting Party without the prior written consent of such Non-Prosecuting Party. The Prosecuting Party shall be reimbursed for any costs and expenses incurred in prosecuting Combined Therapy Patents and the subsequent maintenance of Combined Therapy Patents by the Non-Prosecuting Party such that BMS shall be responsible for fifty percent (50%) of such costs and the Company shall be responsible for fifty percent (50%) of such costs. In case one of the two Parties decides not to file or maintain a Combined Therapy Patent or patent application in a given country, the other Party shall have the right to file or maintain such patent application in such country in its own name and at its own expense. In this case, the Party who decides not to file or maintain a joint application shall promptly assign its rights to the Combined Therapy Patent in said country to the Party who wishes to file or maintain said patent application, unless such Party agrees to reimburse the other Party for its share of the costs of prosecution and maintenance of such Combined Therapy Patent or Combined Therapy Patent application in such country. The Party who does not wish to file or maintain a patent application in any country shall assist in the timely provision of all documents required under national provisions to register said assignment of rights with the corresponding national authorities at the sole expenses of the Party who wishes to file or maintain such patent application in that given country.

5.2 Disclosure and Assignment of Inventions. Each Party shall disclose promptly to the other Party in writing and on a confidential basis all Inventions, prior to any public disclosure or filing of Patent applications thereon and allowing sufficient time for comment by the other Party. In addition, each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions as well as any intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the sole ownership provided for in Section 5.1(a), in the case of a Company

Study Invention, in Section 5.1(b) in the case of a BMS Study Invention, or joint ownership provided for in Section 5.1(c) in the case of a Combined Therapy Study Invention.

5.3 Infringement of Patent Rights by Third Parties

(a) **Notice**. Each Party shall promptly notify the other Party in writing of any known, alleged or threatened infringement or misappropriation by a Third Party of Combined Therapy Patents or any other Patents or intellectual property of either Party material to the Combined Therapy Patents, as well as any declaratory judgment or similar actions alleging the invalidity, unenforceability or non-infringement of Patents on any Combined Therapy Inventions, of which such Party becomes aware (such infringement or action being an "***Infringement***").

(b) **Infringement of Company Study Patents**. For all Infringement of Company Study Patents anywhere in the world, the Company shall have the exclusive right to prosecute such Infringement as it may determine in its sole and absolute discretion, and the Company shall bear all related expenses and retain all related recoveries. BMS shall reasonably cooperate with the Company or its designee (to the extent BMS has relevant information arising out of this Agreement), at the Company's request and expense, in any such action.

(c) **Infringement of BMS Study Patents**. For all Infringement of BMS Study Patents anywhere in the world, BMS shall have the exclusive right to prosecute such Infringement as it may determine in its sole and absolute discretion, and BMS shall bear all related expenses and retain all related recoveries. The Company shall reasonably cooperate with BMS or its designee (to the extent that the Company has relevant information arising out of this Agreement), at BMS' request and expense, in any such action.

(d) **Infringement of Combined Therapy Patents**

(i) The Company shall have the first right to initiate legal action to enforce all Combined Therapy Patents against Infringement by any Third Party that is manufacturing, developing, marketing, or seeking to market the Company Compounds, or any biosimilar version thereof, or to defend any declaratory judgment action relating thereto, at its sole expense. In the event such course of action includes litigation, BMS may choose, at its own expense, to be represented in such action by counsel of its own choice. If BMS is required as a necessary party to such action, each Party shall pay its respective expenses associated therewith.

(ii) BMS shall have the first right to initiate legal action to enforce all Combined Therapy Patents against Infringement by any Third Party that is manufacturing, developing, marketing, or seeking to market BMS Compound or any biosimilar version thereof, or to defend any declaratory judgment action relating thereto, at its sole expense. In the event such course of action includes litigation, the Company may choose, at its own expense, to be represented in such action by counsel of its own choice. If the Company is required as a necessary party to such action, each Party shall pay its respective expenses associated therewith.

(iii) If a Third Party is Infringing any Combined Therapy Patents in a manner other than as set forth above in or Section 5.3(d)(i), and Section 5.3(d)(ii) (i.e., not involving the Company Compounds or any generic or biosimilar version thereof, or BMS Compound or any generic or biosimilar version thereof), then the Parties shall discuss in good faith whether to bring an enforcement action to seek the removal or prevention of such Infringement and damages therefor and, if so, which Party shall bring such action. If the Parties agree to bring such action:

(1) each Party shall keep the other Party reasonably informed as to any legal or commercial courses of action it pursues pursuant to this subsection

(2) each Party shall be responsible for fifty percent (50%) of the total costs and expenses incurred by both Parties in such litigation; and

(iv) Regardless of which Party brings an enforcement action pursuant to this Section 0, the other Party hereby agrees to cooperate reasonably in any such action.

(iv) If either Party recovers monetary damages from any Third Party in an action approved by the Parties, and brought under this Section 5.3(d), such recovery shall be allocated first to the reimbursement of any actual, unreimbursed costs and expenses incurred by the Parties in such litigation pro rata in accordance with the aggregate amounts spent by both Parties, and any remaining amounts shall be split fifty percent (50%) to the Company and fifty percent (50%) to BMS, unless the Parties agree in writing to a different allocation. In connection with any proceeding, neither Party shall enter into any settlement without the prior written consent of the other Party.

5.4 Infringement of Third Party Rights

(a) **Notice**. If the activities relating to the Combined Therapy Study become the subject of a claim of infringement of a patent, copyright or other proprietary right by a Third Party anywhere in the world, the Party first having notice of the claim shall promptly notify the other Party and, without regard to which Party is charged with said infringement and the venue of such claim, the Parties shall promptly confer to discuss the claim.

(b) **Defense**. If both Parties are charged with infringement as described in Section 5.4(a), the Parties shall defend such claim jointly, unless they agree otherwise. If only one Party is charged with such infringement, such Party will have the first right but not the obligation to defend such claim. If the charged Party does not commence actions to defend such claim within thirty (30) calendar days after being notified of such claim, then the other Party shall have the right, but not the obligation, to defend any such claim. In any event, the non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim and shall have the right to participate with separate counsel at its own expense, and the defending Party shall consider comments by the non-defending Party in good faith. The Party defending the claim shall bear the cost and expenses of the defense of any such Third Party infringement claim and shall have sole rights to any recovery. If the Parties jointly defend the claim, the Company shall bear fifty percent (50%), and BMS shall bear fifty percent (50%) of any costs and expenses of the defense of any such Third Party infringement claim; *provided* that, notwithstanding the foregoing, if the claim relates solely to one Party's Compound, such Party will bear one hundred percent (100%) of the costs and expenses of the defense of such claim and shall have the sole right, but not the obligation, to defend, settle and otherwise handle the disposition of such claim. Neither Party shall enter into any settlement concerning activities under this Agreement, or the Combined Therapy that affects the other Party's rights or interests under this Agreement or that imposes any obligations on the other Party, including any admissions of wrongdoing, without such other Party's prior written consent, not to be unreasonably withheld or delayed.

5.5 Combined Therapy Study Regulatory Documentation. Subject to the license and other rights granted by each Party to the other Party pursuant to this Agreement, the Company and BMS shall jointly own all right, title and interest in and to the Combined Therapy Study Regulatory Documentation; *provided* that BMS shall retain sole and exclusive ownership of any BMS Regulatory Documentation provided to the Company under this Agreement that is contained or referenced in the Combined Therapy Study Regulatory Documentation and that the Company shall retain sole and exclusive ownership of any Company Regulatory Documentation that is contained or referenced in the Combined Therapy Study Regulatory Documentation. This Section 5.5 is without limitation of any other disclosure obligations under the Pharmacovigilance Agreement or this Agreement.

Article 6
Costs and Expenses

6.1 Responsibility. With respect to each Sponsor-Funded Study, the Sponsoring Party will bear all out-of-pocket Study Costs as described in Section 6.2 below for the conduct of a Sponsor-Funded Study, and each Party will bear its own FTE Costs in supporting such Sponsor-Funded Study.

6.2 Study Costs. For purposes of this Agreement, "***Study Costs***" means (a) the FTE Cost for the Sponsoring Party FTEs directly supporting a Combined Therapy Study where the Sponsoring Party does not engage a CRO for the conduct of such Combined Therapy Study, and (ii) the out-of-pocket costs reasonably incurred by each Party to Third Party clinical trial sites, CROs and other contractors and vendors for the conduct of the

Combined Therapy Study (including out-of-pocket costs for sourcing any Other Therapy used in the Combined Therapy Study, project management, document management, monitoring and site management, specimen management, laboratory, imaging, investigator grants, site costs, Compound labeling and storage, electronic data capture (EDC), interactive voice response system (IVRS), cost of comparator drugs (as applicable in accordance with the applicable Protocol), consultants, contractors for the testing and screening of patients and lab costs). Study Costs shall also include the out-of-pocket costs of the PD-L1 Expression Testing (and any exploratory biomarker analysis to be conducted by BMS as specified in the Bioanalysis Plan), and the out-of-pocket costs of the Biomarker Testing (and any exploratory biomarker analysis to be conducted by the Company as specified in the Bioanalysis Plan).

6.3 Payments to Third Parties. For avoidance of doubt, Study Costs will not include Third Party License Payments by a Party or Third Party Claims. Also, for clarity, expenses incurred as described in Article 4 (regarding Manufacturing and supply) and Article 5 (regarding Patents) shall be borne or shared by the Parties as provided in such Articles, and not included in the Study Costs. Except as mutually agreed by the Parties, each Party shall be solely responsible for all of its own internal costs incurred by such Party or any of its Affiliates in connection with the conduct of the Combined Therapy Study.

Article 7
Records and Study Data

7.1 Records. Each Party shall maintain complete and accurate records of all work conducted with respect to the Combined Therapy Study and of all results, information, data, data analyses, reports, records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences and developments made by or provided to either Party, or by the Parties together, in the course of such Party(ies)' efforts with respect to the Combined Therapy Study (including the Statistical Analysis Plan and any Bioanalysis Plan to be conducted pursuant to this Agreement) (such Combined Therapy results, information, data, data analyses, reports, CRFs, adverse event reports, trial records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, developments, and the Combined Therapy Study protocol, all as and to the extent developed or used in connection with Combination Therapy, referred to as the "***Study Data***"). Such records shall fully and properly reflect all work done and results achieved in the performance of the Combined Therapy Study in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

7.2 Ownership of Study Data. BMS shall own the Study Data to the extent that it relates solely to the BMS Compound ("***BMS Study Data***"), and the Company shall own the Study Data to the extent that it relates solely to the Company Compounds ("***Company Study Data***"). Subject to the restrictions on use and disclosure as set forth in this Agreement, both Parties shall jointly own any Study Data that is not BMS Study Data or Company Study Data (such jointly owned Study Data being the "***Combined Therapy Study Data***"). Each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Study Data as is necessary to fully effect the foregoing, and agrees to execute all instruments as may be reasonably necessary to effect same.

7.3 Use of a Party's Own Study Data. BMS may use, analyze and disclose to Third Parties the BMS Study Data for any purpose without obligation or accounting to the Company. The Company may use, analyze and disclose to Third Parties the Company Study Data for any purpose without obligation or accounting to BMS.

7.4 Use of Combined Therapy Study Data by BMS

(a) Subject to the restrictions on disclosure of the Combined Therapy Study Data to Third Parties as set forth below in this Section 7.4, BMS shall have the right to use and analyze the Combined Therapy Study Data for any purpose.

(b) The Combined Therapy Study Data shall not be disclosed to Third Parties by BMS except as follows (and otherwise as expressly permitted under the Agreement):

(i) BMS may disclose the Combined Therapy Study Data to a Bona Fide Collaborator, solely for purposes of the development, regulatory approval and commercialization of the one or more compounds or products that are the subject of the bona fide contractual licensing arrangement with such Bona Fide Collaborator; provided such Bona Fide Collaborator shall be subject to the same restrictions on use and disclosure of such Combined Therapy Study Data as BMS under this Agreement; and provided further that disclosure of such Combined Therapy Study Data does not grant to such Bona Fide Collaborator any intellectual property rights in and to the Company Technology, Company Inventions, Company Study Data or the Company Compounds or any Right of Cross-Reference to Company Regulatory Documentation.

(ii) BMS may disclose the Combined Therapy Study Data to its contractors under confidentiality obligations similar to BMS' obligations under the Agreement, solely for purposes and to the extent required for such contractors to provide services for BMS for the development, regulatory approval and/or commercialization of the BMS Compound.

(iii) BMS may disclose the Combined Therapy Study Data (1) to Regulatory Authorities in connection with regulatory filings, (y) to investigators as necessary in connection with the Combined Therapy Study (provided that BMS shall provide the Company with at least five (5) Business Days' notice prior to any such disclosure) or (2) as may be required by Applicable Law.

(iv) To the extent that the Combined Therapy Study Data includes Safety Information and BMS needs to disclose to Third Parties such Safety Information of the Combined Therapy in its studies of the BMS Compound with other Conditionally Active Biologic Antibody Drug Conjugates (CAB ADC) in order to ensure patient safety, BMS may disclose such Safety Information. For clarity, BMS shall not disclose Safety Information related solely to one or both of the Company Compounds.

(v) BMS may use and disclose to a Third Party the Combined Therapy Study Data, under obligations of confidentiality consistent with this Agreement, to the extent such Third Party is developing or commercializing a biomarker or diagnostic test for use with its Compound or the Combined Therapy as but only to the extent either (A) as monotherapy (without use or reference to any other pharmaceutical compound or therapeutic agent) or (B) as part of Combined Therapy under this Agreement.

(vi) Filing or prosecuting Patent Rights for Inventions.

7.5 Use of Combined Therapy Study Data by the Company

(a) Subject to the restrictions on disclosure of the Combined Therapy Study Data to Third Parties as set forth below in this Section 7.5, the Company shall have the right to use and analyze the Combined Therapy Study Data for any purpose.

(b) The Combined Therapy Study Data shall not be disclosed to Third Parties by the Company except as follows (and otherwise as expressly permitted under the Agreement).

(i) The Company may disclose the Combined Therapy Study Data to a Bona Fide Collaborator solely for purposes of the development, regulatory approval and commercialization of the one or more compounds or products that are the subject of the bona fide contractual licensing arrangement with such Bona Fide Collaborator; provided such Bona Fide Collaborator shall be subject to the same restrictions on use and disclosure of such Combined Therapy Study Data as BMS under this Agreement; and provided further that disclosure of such Combined Therapy Study Data does not grant to such Bona Fide Collaborator any intellectual property rights in and to the BMS Technology, BMS Inventions, BMS Study Data or the BMS Compound or any Right of Cross-Reference to BMS Regulatory Documentation.

(ii) The Company may disclose the Combined Therapy Study Data to its contractors under confidentiality obligations similar to the Company's obligations under the Agreement, solely for purposes and to the extent required for such contractors to provide services for the Company for the development, regulatory approval and/or commercialization of the Company Compounds.

(iii) The Company may disclose the Combined Therapy Study Data (1) to Regulatory Authorities in connection with regulatory filings, (2) to investigators as necessary in connection with the Combined Therapy Study (provided that the Company shall provide BMS with at least five (5) Business Days' notice prior to any such disclosure) and/or (3) as may be required by Applicable Law.

(iv) To the extent that the Combined Therapy Study Data includes Safety Information and the Company needs to disclose to Third Parties such Safety Information of the Combined Therapy in its studies of the Company Compounds with other PD-1 antagonists in order to ensure patient safety, the Company may disclose such Safety Information solely for such purposes. For clarity, the Company shall not disclose Safety Information related solely to the BMS Compound.

(v) The Company may use and disclose to a Third Party the Combined Therapy Study Data, under obligations of confidentiality consistent with this Agreement, to the extent such Third Party is developing or commercializing a biomarker or diagnostic test for use with its Compound and/or the Combined Therapy as but only to the extent either (i) as monotherapy (without use or reference to any other pharmaceutical compound or therapeutic agent) or (ii) as part of Combined Therapy under this Agreement.

(vi) Filing or prosecuting Patent Rights for Inventions.

7.6 No Other Uses. All other uses of Study Data are limited solely to those permitted by this Agreement, and neither Party may use Study Data for any other purpose without the consent of the other Party during and after the Term.

7.7 Access to Study Data. In accordance with the terms and conditions of this Agreement and the Pharmacovigilance Agreement, the Other Party shall have access to all Study Data (including the results of the PD-L1 Expression Testing of Samples and Biomarker Testing of Samples (including de-identified patient records)) in a timely manner in accordance with Section 2.5.

7.8 Samples

(a) Samples collected from Combined Therapy Study subjects shall be jointly owned by the Parties (to the extent not owned by the patient and/or the clinical trial site). Any such Samples shall be collected in accordance with the applicable Protocol and ICFs. Except as set forth in a Bioanalysis Plan, including PD-L1 Expression Testing and Biomarker Testing, neither Party shall be permitted to use the Samples for any purpose without the prior written consent of the other Party, which consent shall not be unreasonably withheld if such use is related to the Combined Therapy (with the terms of such use to be set forth in a written agreement between the Parties setting forth the Samples to be used, and any appropriate terms or restrictions on such use).

(b) Subject to Article 5 and Article 7, any data and Inventions (and Patent Rights claiming such Inventions) arising out of the permitted testing of the Samples shall be owned by the Party conducting such testing, *provided* that to the extent that any such data or Inventions (and Patent Rights claiming such Inventions) relates solely to the Combined Therapy (or biomarkers solely for use solely with the Combined Therapy), such data or Inventions (and Patent Rights claiming such Inventions) shall be considered Combined Therapy Study Data or Combined Therapy Inventions (and Combined Therapy Patents), as the case may be.

(c) The Parties will jointly decide on the future selection of the repository for the Samples. If the Party holding the Samples determines that it no longer has a use for the Samples and the other Party determines that it does, then the Samples shall, subject to Applicable Law and the terms of the signed ICFs, be transferred to the other Party and may be used solely thereafter by the other Party. If neither Party has any further use for the Samples, then the remaining Samples will be destroyed pursuant to the respective Party's standard operating procedures for sample retention and destruction, subject to the terms of and permission(s) granted in the ICFs signed by the subjects contributing the Samples in the Combined Therapy Study.

7.9 NDAs and BLAs and Foreign Equivalents. Notwithstanding either Party's ownership of (i) a Combined Therapy IND as set forth in Section 2.1(g) or (ii) Regulatory Documentation associated with a Combined

Therapy IND, unless otherwise agreed by the Parties and reflected in writing, and pursuant to a regulatory submission strategy:

(a) The Parties (including their respective Affiliates and licensees), after top line results are provided per Section 2.4(q), will enter into good faith discussions to determine a regulatory submission strategy agreeable to both Parties for the applicable Combined Therapy indication. [***].

(b) The sponsor of record in the case of mutual agreement, or the Filing Party in the case where agreement is not reached, shall prepare all Regulatory Documentation for any new or supplemental BLA or NDA and its foreign equivalent to be filed for a Combined Therapy arising from a Combined Therapy Trial in the applicable jurisdiction outside the United States. The sponsor of record in the case of mutual agreement, or the Filing Party in the case where agreement is not reached, shall have primary responsibility, and shall have the first right but not the obligation, to file and maintain (directly or through its designee) any new or supplemental BLA or NDA and its foreign equivalent to be filed for a Combined Therapy arising from a Combined Therapy Trial for each Regulatory Authority (i.e., for each country or region) in the applicable jurisdiction outside the United States; provided that the other Party (x) shall have the right to review and comment on all such Regulatory Documentation prior to such filing, as well as communications with Regulatory Authorities, (y) shall receive a complete, final copy of such Regulatory Documentation prior to such filing, and (z) shall have the right but not the obligation to file all such Regulatory Documentation on its own behalf concurrently or at any time thereafter.

(c) For clarity, in the case of mutual agreement or in the case where agreement is not reached, each Party agrees to: (a) provide to the Filing Party prompt, reasonable consultation and assistance with the preparation, filing and submission of Regulatory Documentation with the Regulatory Authorities both in the United States and outside the United States; and (b) complete all document requests by the Filing Party reasonably required for such Regulatory Documentation, consistent with the Parties' obligations under Sections 2.1(h), within a reasonable time period.

Article 8
Confidentiality

8.1 Nondisclosure of Confidential Information. Prior to the Effective Date, the Company and BMS entered into a certain Mutual Confidentiality Agreement dated January 12, 2021, as amended (the "***CDA***"). Any information previously disclosed by the Parties pursuant to the CDA that is related to or otherwise used in connection with a Combined Therapy Study shall now be Confidential Information for purposes of this Agreement and the Parties shall treat it as such in accordance with the terms hereof, and such information shall be subject to the terms and conditions of this Agreement and shall no longer be subject to the CDA. All written, visual, oral and electronic data, information, know-how or other proprietary information or materials, both technical and non-technical, disclosed by one Party to any other Party pursuant to this Agreement that if in tangible form, is labeled in writing as "proprietary" or "confidential" (or similar reference), or if in oral or visual form, is identified as proprietary or confidential or for internal use only at the time of disclosure or within thirty (30) calendar days thereafter shall be "***Confidential Information***" of the disclosing Party, and all Study Data and Inventions shall be the Confidential Information of the Party owning such Study Data or Invention (as provided in Section 7.2 with regard to Study Data and Section 5.1 with regard to Inventions). For purposes of this Agreement, regardless of which Party discloses such Confidential Information to the other, all Company Study Inventions, Company Technology, and Company Regulatory Documentation shall be Confidential Information of the Company and BMS shall be the receiving Party, and all BMS Study Inventions, BMS Technology, and BMS Regulatory Documentation shall be Confidential Information of BMS and the Company shall be the receiving Party. Except to the extent expressly authorized in this Section 8.1 and Sections 8.2, 8.3, 7.4, and 7.5, or as otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of seven (7) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information owned solely by the other Party, treat the other Party's Confidential

Information with the same degree of care the receiving Party uses for its own confidential information but in no event with less than a reasonable degree of care, and reproduce the disclosing Party's Confidential Information solely to the extent necessary to perform the receiving Party's obligations (or to exercise its rights) under this Agreement, with all such reproductions being considered the disclosing Party's Confidential Information. Notwithstanding anything to the contrary in this Section 8.1, and subject to Sections 7.4, and 7.5, the receiving Party may disclose the disclosing Party's Confidential Information to its employees, consultants, agents or permitted sublicensees for the purpose of fulfilling the receiving Party's obligations (or exercising its rights) under this Agreement; *provided* that any such employees, consultants, agents or permitted sublicensees are bound by obligations of confidentiality similar to those set forth in this Agreement, and the receiving Party remains liable for the compliance of such employees, consultants, agents or permitted sublicensees with such obligations.

8.2 Exceptions. The obligations in Section 8.1 shall not apply with respect to any portion of Confidential Information that the receiving Party can demonstrate by contemporaneous tangible records or other competent proof:

(a) was already known to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, either (i) at the time of disclosure by the disclosing Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(b) was generally available to the public or otherwise part of the public domain either (i) at the time of its disclosure to the receiving Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(c) became generally available to the public or otherwise part of the public domain after its disclosure or generation and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, by a Third Party who had no obligation to the Party owning or Controlling the information not to disclose such information to others; or

(e) was independently discovered or developed by the receiving Party (or its Affiliates) without the use of or reference to the Confidential Information belonging to the disclosing Party.

8.3 Authorized Disclosure. Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is necessary in the following instances:

(a) filing or prosecuting Patent Rights with respect to any Inventions;

(b) prosecuting or defending litigation brought in connection with any Third Party Claim or under the terms of this Agreement;

(c) complying with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock is listed;

(d) disclosure, in connection with the performance of this Agreement, to Affiliates, permitted sublicensees, contractors, ethics committees and IRBs, CROs, academic institutions, consultants, agents, investigators, and employees and contractors engaged by Study Sites and investigators involved with the Combined Therapy Study and who have a need to know such information in connection with the proper performance the Combined Therapy Study, each of whom prior to disclosure must be bound in writing by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 8, where such period of confidentiality shall last for time period stated in Section 8.1;

(e) disclosure of the Combined Therapy Study Data, Combined Therapy Inventions and Combined Therapy Patents to Regulatory Authorities in connection with the development of the Combined Therapy, the Company Compounds (in the case of the Company) or the BMS Compound (in the case of BMS);

(f) disclosure of Combined Therapy Study Data in accordance with Section 7.4 or Section 7.5 (as applicable); and

(g) disclosure of relevant Safety Information contained within the Combined Therapy Study Data to investigators, institutional review boards and/or ethics committees and Regulatory Authorities that are involved in other clinical trials of either or both of the Company Compounds with respect to the Company, and the BMS Compound with respect to BMS, and (in the event of a Material Safety Issue) to Third Parties that are collaborating with the Company or BMS, respectively in the conduct of such other clinical trials of the Company Compounds or the BMS Compound, in each case solely to the extent necessary for the proper conduct of such clinical trials and/or to comply with Applicable Law and regulatory requirements.

Notwithstanding the foregoing, if a Party is required or otherwise intends to make a disclosure of the other Party's Confidential Information pursuant to Section 8.3(b), or Section 8.3(c), it shall give advance notice to such other Party of such impending disclosure and endeavor in good faith to secure confidential treatment of such Confidential Information and/or reasonably assist the Party that owns such Confidential Information in seeking a protective order or other confidential treatment. If a Party intends to make a disclosure of the other Party's Confidential Information pursuant to Section 9.1(a), it shall give advance notice to such other Party of such intended disclosure, and the Parties shall cooperate with respect to the timing and secure the other Party's permission to make such disclosure taking into account the non-disclosing Party's plans for Patent filings on Inventions in accordance with Section 5.1.

8.4 Disclosure to Ono. Notwithstanding any other provision of this Agreement, the Company hereby expressly authorizes BMS to disclose to Ono (a) the existence and terms of this Agreement, the Combined Therapy Study and the Protocols, (b) the BMS Study Data and the Combined Therapy Study Data and (c) any Confidential Information, solely as necessary for BMS to fulfill its obligations to Ono under the Ono-BMS Agreement with respect to the BMS Compound; *provided* that Ono is subject to written confidentiality obligations at least as restrictive as set forth herein.

8.5 Press Releases and Publications

(a) Except as contemplated by the proviso to the final sentence in this Section 8.5(a), neither Party may issue any external communication, including, without limitation, an initial press release to be issued by the Company, subsequent press releases, Q&As, and the content and wording for of any listing of the Combined Therapy Study required to be listed on a public database or other public registry such as www.clinicaltrials.gov unless agreed to in writing by the other Party If the Parties agree to issue an external communication, the Parties shall also agree to the content and timing of such external communication. Notwithstanding the foregoing, information contained in external communications previously approved by the Parties may be included in subsequent external communications (but not subsequent press releases, which shall be subject to review and approval by the Parties in accordance with this Section 8.5(a)) by either Party without review by, or the necessity to obtain prior approval from, the other Party. For clarity, if either Party terminates this Agreement pursuant to Section 11.3, the Parties shall mutually agree upon any external communication related to such termination, which shall not include the rationale for such termination unless (and to the extent) mutually agreed by the Parties; *provided* that either Party shall be permitted to publicly disclose information that such Party determines in good faith is necessary to be disclosed to comply with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock may be listed, or pursuant to an order of a court or governmental entity.

(b) The Company and BMS agree to collaborate to publicly disclose, publish or present (i) top-line results from the Combined Therapy Study, limited if possible to avoid jeopardizing the future publication of the Study Data at a scientific conference or in a scientific journal, solely for the purpose of disclosing, as soon as reasonably practicable, the safety or efficacy results and conclusions that are material to either Party under

applicable securities laws, and (ii) the conclusions and outcomes (the "***Results***") of the Combined Therapy Study at a scientific conference as soon as reasonably practicable the completion of such Combined Therapy Study, subject in the case of (ii) to the following terms and conditions. The Sponsoring Party shall take the lead in drafting the first joint abstract, presentation or publication of the interim (as appropriate) and final Results of any of the Combined Therapy Study. Thereafter, both Parties shall have the right to propose disclosure, publication or presentation of the previously disclosed Results. The Party proposing to disclose, publish or present the Results shall deliver to the other Party a copy of the proposed disclosure or publication at least thirty (30) calendar days before submission to a Third Party, or, in the case of any abstract, poster or presentation at least fifteen (15) calendar days before submission to a Third Party. The reviewing Party shall determine whether any of its Confidential Information that may be contained in such disclosure, publication, abstract, poster or presentation should be modified or deleted, whether to file a patent application on any Company Study Invention (solely with respect to the Company) or BMS Study Invention (solely with respect to BMS) or Combined Therapy Invention disclosed therein. The disclosure, publication or presentation shall be delayed for up to an additional thirty (30) calendar days (i.e., a total of up to sixty (60) calendar days from the initial proposal) if the reviewing Party reasonably requests such extension to allow time for the preparation and filing of relevant patent applications. If the reviewing Party reasonably requests modifications to the disclosure, publication, abstract, poster or presentation to prevent the disclosure of a material trade secret or proprietary business information, the publishing Party shall edit such publication to prevent the disclosure of such information prior to submission of the disclosure, publication, abstract, poster or presentation. In the event of a disagreement as to content, timing and/or venue or forum for any disclosure, publication or presentation of the Results, such dispute (a "***Publication Dispute***") shall be referred to the Executive Officers (or their respective designees); *provided* that, in the absence of agreement after such good faith discussions, and upon expiration of the thirty (30) calendar day period (or as applicable up to sixty (60) calendar day period) as outlined above, academic collaborators engaged by the Company in connection with the performance of the Combined Therapy Study may publish Combined Therapy Study Data obtained by such academic collaborator solely to the extent that such ability to publish such Combined Therapy Study Data is set forth in an agreement between the Company and such academic collaborator relating to the conduct of Combined Therapy Study. Authorship of any publication shall be determined based on the accepted standards used in peer-reviewed academic journals at the time of the proposed disclosure, publication or presentation. The Parties agree that they shall make reasonable efforts to prevent publication of a press release that could jeopardize the future publication of Study Data at a scientific conference or in a scientific journal but in no way will this supersede the requirements of any Applicable Law or the rules or regulations of any securities exchange or listing entity on which a Party's stock is listed.

8.6 Compliance with Sunshine Laws. For purposes of compliance with reporting obligations under Sunshine Laws, as between the Parties, the applicable Sponsoring Party will report all payments or other transfers of value ("***POTV***") made by or on behalf of the Sponsoring Party related to the conduct of the Combined Therapy Study and any applicable associated contractor engagements. Interpretation of the Sunshine Laws for purposes of reporting any POTV shall be in the Sponsoring Party's sole discretion. The Sponsoring Party will also provide the Other Party with any information reasonably requested by the Other Party for the Other Party to comply with its reporting obligations under Sunshine Laws. For purposes of this Section 8.6, "***Sunshine Laws***" means Applicable Laws requiring disclosure of POTVs to certain healthcare providers, entities and individuals, including Section 6002 of the Patient Protection and Affordable Health Care Act of 2010 and implementing regulations thereunder.

8.7 Patient Privacy and Data Protection

(a) Each Party shall comply with Applicable Laws relating to patient privacy and data protection. Such compliance includes obtaining, in a manner consistent with Applicable Law, consent from each Study subject to provide such subject's personally identifiable information to the Study doctor for purposes of the study. Such information will be de-identified in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and local data protection laws and will be used by the Sponsoring Party and its representatives, collaborators (including, as applicable, the Other Party and its Affiliates) and licensees for the purposes of (a) conducting the applicable Combination Therapy Study, and performing the Sample analysis required under the

Bioanalysis Plan, including PD-L1 Expression Testing and Biomarker Testing, if any, (b) conducting research directly related to the health condition under investigation pursuant to the Protocol and related diseases, (c) using the BMS Compound and the Company Compounds in disease therapy or diagnosis, and (d) inspecting records or facilities relevant to the Combination Therapy Study. Each Party agrees that it shall not disclose in any publication, information that would reveal the identity of a subject (such as name, photograph, social security number, telephone number or address), without the written consent of such subject.

(b) Subject to the terms of this Agreement, and prior to the exchange of personal data pursuant to this Agreement, the Company and BMS shall define and finalize the responsibilities of the Parties with respect to the control, processing and transfer of personal data pursuant to this Agreement. These responsibilities shall include mutually acceptable guidelines and procedures for the processing, receipt, investigation, recordation, communication, and exchange (as between the Parties) and regulatory submission of personal data pursuant to this Agreement. Such agreed procedures shall be consistent with the General Data Protection Regulation (EU) 2016/679. All such agreed responsibilities, guidelines and procedures shall be set forth in a written data processing agreement between the Parties and supported by the appropriate mechanism for the transfer of personal data.

8.8 Destruction of Confidential Information. Upon expiration or termination of the Agreement, the receiving Party shall, upon request by the other Party, immediately destroy or return all of the other Party's Confidential Information relating solely to its Compound (but not to the Combined Therapy or the Combined Therapy Study data) in its possession; *provided* that the receiving Party shall be entitled to retain one (1) copy of Confidential Information solely for record-keeping purposes and shall not be required to destroy any off-site computer files created during automatic system back up which are subsequently stored securely by the receiving Party.

Article 9
Representations and Warranties

9.1 Authority and Binding Agreement. Each Party represents and warrants to the other Party that (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (c) the Agreement has been duly executed and delivered on behalf of each Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms subject to bankruptcy, insolvency, reorganization, arrangement, winding-up, moratorium, and similar laws of general application affecting the enforcement of creditors' rights generally, and subject to general equitable principles, including the fact that the availability of equitable remedies, such as injunctive relief or specific performance, is in the discretion of the court.

9.2 No Conflicts. Each Party represents and warrants to the other Party that, to the best of its knowledge, it has not entered, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to the other Party under this Agreement, and has not taken any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement, or that would otherwise materially conflict with or adversely affect the rights granted to the other Party under this Agreement. BMS represents and warrants that (a) nothing in this Agreement conflicts with its obligations under the Ono-BMS Agreement, and BMS' performance of its obligations hereunder will not result in any breach of obligations under the Ono-BMS Agreement, and (b) as of the Effective Date, it is not in breach of any of its obligations under the Ono-BMS Agreement that would (with notice and the passage of time or otherwise) give rise to a termination right under the Ono Agreement. Each Party represents and warrants to the other Party that, to its knowledge as of the Effective Date, the practice of the licenses granted herein do not infringe any Patents of a Third Party.

9.3 Litigation. Each Party represents and warrants to the other Party that, to the best of its knowledge, it is not aware of any pending or threatened litigation (and has not received any communication) that alleges that its activities related to this Agreement have violated, or that by conducting the activities as contemplated in this

Agreement it would violate, any of the intellectual property rights of any other Person (after giving effect to the license grants in this Agreement).

9.4 No Adverse Proceedings. Each Party represents and warrants to the other Party that except as otherwise notified to the other Party in writing as of the Effective Date, there is not pending or, to the knowledge of the Party making the representation and warranty, threatened, against such Party, any claim, suit, action or governmental proceeding that would, if adversely determined, materially impair the ability of such Party to perform its obligations under this Agreement.

9.5 Consents. Each Party represents and warrants to the other Party that, to the best of its knowledge, all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons (a) required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained (or will have been obtained prior to such execution and delivery) and (b) required to be obtained by such Party in connection with the performance of its obligations under this Agreement have been obtained or will be obtained prior to such performance.

9.6 No Debarment. Each Party hereby certifies to the other Party that it has not used, and will not knowingly use the services of any person disqualified, debarred, banned, subject to debarment or convicted of a crime for which a person could be debarred by the FDA under 21 U.S.C. 335a, as amended (or subject to a similar sanction of any other Regulatory Authority), in any capacity in connection with any of the services or work provided under the Combined Therapy Study and that this certification may be relied upon in any applications to the FDA or any other Regulatory Authority. It is understood and agreed that this certification imposes a continuing obligation upon each Party to notify the other promptly of any change in the truth of this certification. Upon request by a Party, the other Party agrees to provide a list of persons used to perform the services or work provided under any activities conducted for or on behalf of such Party or any of its Affiliates pursuant to this Agreement who, within the five years preceding the Effective Date, or subsequent to the Effective Date, were or are convicted of one of the criminal offenses required by 21 U.S.C. 335a, as amended, to be listed in any application for approval of an abbreviated application for drug approval.

9.7 Compliance with Applicable Law. Each Party represents and warrants to the other Party that it shall comply in all material respects with all Applicable Law of the country or other jurisdiction, or any court or agency thereof, applicable to the performance of its activities hereunder or any obligation or transaction hereunder, including those pertaining to the production and handling of drug products, such as those set forth by the Regulatory Agencies, as applicable, and the applicable terms of this Agreement, in the performance of its obligations hereunder.

9.8 Affiliates. Each Party represents and warrants to the other Party that, to the extent the intellectual property, Regulatory Documentation or Technology licensed by it hereunder are Controlled by its Affiliates or a Third Party, it has the right to use, and has the right to grant (sub)licenses to the other Party to use, such intellectual property, Regulatory Documentation or Technology in accordance with the terms of this Agreement.

9.9 Ethical Business Practices. Each Party represents and warrants to the other Party that (a) neither it nor its Affiliates will make any payment, either directly or indirectly, of money or other assets, including the compensation such Party derives from this Agreement (collectively a "***Payment***"), to government or political party officials, officials of International Public Organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (collectively "***Officials***") where such Payment would constitute violation of any law, including the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1, et seq. In addition, regardless of legality, neither it nor its Affiliates will make any Payment either directly or indirectly to Officials if such Payment is for the purpose of improperly influencing decisions or actions with respect to the subject matter of this Agreement and (b) all activities conducted by, for or on behalf of such Party will be conducted in compliance with the U.S. False Claims Act and the U.S. Anti-Kickback Statute.

9.10 Compound Safety Issues. Each Party represents and warrants to the other Party that, to the best of its knowledge as of the Effective Date, it is not aware of any material safety data relating to its Compound,

whether alone or in combination with any other agent, that either has not already been communicated to the other Party or is not reflected in the investigator's brochure for its Compound existing as of the Effective Date.

9.11 Accounting. Each Party represents and warrants to the other Party that all transactions under the Agreement shall be properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects.

9.12 DISCLAIMER OF WARRANTY. THE EXPRESS REPRESENTATIONS AND WARRANTIES STATED IN THIS ARTICLE 9 ARE IN LIEU OF, AND THE PARTIES DO HEREBY DISCLAIM, ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

Article 10
Insurance; Indemnification; Limitation of Liability

10.1 BMS Indemnification. BMS hereby agrees to defend, hold harmless and indemnify (collectively, "***Indemnify***") the Company, its Affiliates, and its and their agents, directors, officers, and employees (the "***Company Indemnitees***") from and against any and all liabilities, expenses or losses, including without limitation reasonable legal expenses and attorneys' fees (collectively "***Losses***") resulting from Third Party suits, claims, actions and demands (each, a "***Third Party Claim***") to the extent that they arise or result from (a) the negligence or intentional misconduct of BMS, any BMS Indemnitee or any sublicensee of BMS conducting activities on behalf of BMS under this Agreement, (b) any breach by BMS of any provision of this Agreement, (c) any injury to a subject in a Combined Therapy Study clinical trial to the extent caused by the development, use or manufacture of the BMS Compound, (d) any injury to a subject in a Combined Therapy Study clinical trial where it ultimately cannot be or is not determined if such injury is the direct result of the BMS Compound on the one hand or the relevant Company Compound on the other hand, *provided* that, in the case of this clause (d), BMS shall only Indemnify the Company Indemnitees for fifty percent (50%) of any such Loss, or (e) the use by BMS of Study Data or Inventions outside the scope of this Agreement, excluding Third Party Claims that are covered under Section 5.4; but excluding, in each case ((a) through (e)), any such Losses to the extent that the Company is obligated to Indemnify the BMS Indemnitees pursuant to Section 10.2.

10.2 Company Indemnification. The Company hereby agrees to Indemnify BMS, its Affiliates, and its and their agents, directors, officers, and employees (the "***BMS Indemnitees***") from and against any and all Losses resulting from Third Party Claims to the extent that they arise or result from (a) the negligence or intentional misconduct of the Company or any Company Indemnitee or any sublicensee of the Company conducting activities on behalf of the Company under this Agreement, (b) any breach by the Company of any provision of this Agreement; (c) any injury to a subject in a Combined Therapy Study clinical trial to the extent caused by the development, use or manufacture of the relevant Company Compound, (d) any injury to a subject in a Combined Therapy Study clinical trial where it ultimately cannot be or is not determined if such injury is the direct result of the relevant Company Compound on the one hand or the BMS Compound on the other hand; *provided* that, in the case of this clause (d), the Company shall only Indemnify the BMS Indemnitees for fifty percent (50%) of any such Loss, or (e) the use by the Company of Study Data or Inventions outside the scope of this Agreement, excluding Third Party Claims that are covered under Section 5.4; but excluding, in each case ((a) through (e)), any such Losses to the extent BMS is obligated to Indemnify the Company Indemnitees pursuant to Section 10.1.

10.3 Indemnification Procedure. Each Party's agreement to Indemnify the other Party is conditioned on the performance of the following by the Party seeking indemnification: (a) providing written notice to the Indemnifying Party of any Loss of the types set forth in Sections 10.1 and 10.2 within sixty (60) calendar days after the Party seeking indemnification has knowledge of such Loss; *provided* that, any delay in complying with the requirements of this clause (a) will only limit the Indemnifying Party's obligation to the extent of the prejudice caused to the Indemnifying Party by such delay, (b) permitting the Indemnifying Party to assume full responsibility

to investigate, prepare for and defend against any such Loss, (c) providing reasonable assistance to the Indemnifying Party, at the Indemnifying Party's expense, in the investigation of, preparation for and defense of any Loss, and (d) not compromising or settling such Loss without the Indemnifying Party's written consent, such consent not to be unreasonably withheld or delayed.

10.4 Separate Defense of Claims. In the event that the Parties cannot agree as to the application of Sections 10.1, 10.2, or 10.3 to any particular Loss, the Parties may conduct separate defenses of such Loss. Each Party further reserves the right to claim indemnity from the other in accordance with Sections 10.1, 10.2, or 10.3 upon resolution of the underlying claim, notwithstanding the provisions of Section 10.3(b).

10.5 Insurance. Each Party shall maintain commercially reasonable levels of insurance or other adequate and commercially reasonable forms of protection or self-insurance that are consistent with customary practices in the industry in order to satisfy its indemnification obligations under this Agreement. Each Party shall provide the other Party with written notice at least thirty (30) calendar days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which would materially adversely affect the rights of the other Party hereunder.

10.6 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY OR OTHERWISE). NOTHING IN THIS SECTION 10.5 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER SECTIONS 10.1 OR 10.1, OR DAMAGES AVAILABLE FOR BREACHES OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 8.

Article 11
Term and Termination

11.1 Term. This Agreement shall be effective as of the Effective Date and, unless earlier terminated pursuant to Sections 11.2(b), 11.2(c), 11.3, or any other termination right expressly provided for elsewhere in this Agreement, shall continue, on a Combined Therapy Study-by-Combined Therapy Study basis, in effect until completion and delivery to both Parties of all case report forms, completion of the Statistical Analysis Plan analyses and all final clinical study reports contemplated by each Combined Therapy Study (the "***Term***").

11.2 Termination for Material Breach

(a) **Notice and Cure Period.** If a Party (the "***Breaching Party***") is in material breach, the other Party (the "***Non-Breaching Party***") shall have the right to give the Breaching Party notice specifying the nature of such material breach. The Breaching Party shall have a period of sixty (60) calendar days after receipt of such notice to cure such material breach (the "***Cure Period***") in a manner reasonably acceptable to the Non-Breaching Party. For the avoidance of doubt, this provision is not intended to restrict in any way either Party's right to notify the other Party of any other breach or to demand the cure of any other breach.

(b) **Termination Right.** The Non-Breaching Party shall have the right to terminate this Agreement (i) on a Combined Therapy Study-by-Combined Therapy Study basis if such breach is solely related to such Combined Therapy Study or (ii) the Agreement as a whole if (A) the breach applies to all Combined Therapy Studies, (B) any breach of Article 8, in each case upon written notice, in the event that the Breaching Party has not cured such material breach within the Cure Period, *provided* that if such breach is capable of cure but cannot be cured within the Cure Period despite the use of diligent efforts, and the Breaching Party notifies the Non-Breaching Party of its intent to cure and commences actions to cure such material breach within the Cure Period and thereafter diligently continues such actions, the Breaching Party shall have an additional thirty (30) calendar days to cure such breach. If a Party contests such termination pursuant to the dispute resolution procedures under Section 12.3, such

termination shall not be effective until a conclusion of the dispute resolution procedures in Section 12.3, as applicable, resulting in a determination that there has been a material breach that was not cured within the Cure Period (or, if earlier, abandonment of the dispute by such Party).

(c) **Termination for Bankruptcy**. Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of such other Party's assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within sixty (60) calendar days after the filing thereof, or if the other Party will propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

11.3 Termination Due to Material Safety Issue. Either Party shall have the right to terminate this Agreement as applied to a particular Combined Therapy Study immediately upon written notice if it is necessary to protect the safety, health or welfare of subjects enrolled in such Combined Therapy Study due to the existence of a Material Safety Issue. In the event of a termination due to a Material Safety Issue, prior to the terminating Party providing written notice, the Party's Executive Officers shall, to the extent practicable, meet and discuss in good faith the safety concerns raised by the terminating Party and consider in good faith the input, questions and advice of the non-terminating Party, but should any dispute arise in such discussion, the dispute resolution processes set forth in Section 12.3 shall not apply to such dispute and the terminating Party shall have the right to issue such notice and such termination shall take effect without the Parties first following the procedures set forth in Section 12.3. Notwithstanding the foregoing, a complete Clinical Hold (not partial) with respect to either the BMS Compound or both of the Company Compounds at any time after the Effective Date shall be deemed to be sufficient grounds for a Party to terminate this Agreement with respect to a particular Combined Therapy Study immediately pursuant to this Section 11.3. If a partial Clinical Hold with respect to either a BMS Compound or either or both of the Company Compounds should arise at any time after the Effective Date, the Parties will promptly meet and discuss the basis for the partial Clinical Hold, how long the partial Clinical Hold is expected to last and how they might address the issue that caused the partial Clinical Hold; provided that either Party may terminate this Agreement if such Clinical Hold persists for ninety (90) days and such Party concludes that such Clinical Hold will result in material additional costs or material delays in the conduct of the Combination Therapy Study.

11.4 Effect of Termination. Upon expiration or termination of this Agreement (as a whole or with respect to a particular Combined Therapy Study), (a) the licenses granted to each Party to conduct the terminated Combined Therapy Study under Sections 3.1 and 3.2 shall terminate solely with respect to such terminated Combined Therapy Study(ies) (and, for clarity, shall survive with respect to other Combined Therapy Studies), and (b) the Parties shall use reasonable efforts to wind down activities under this Agreement with respect to the terminated Combined Therapy Studies in a reasonable manner and avoid incurring any additional expenditures or non-cancellable obligations; *provided* that the Sponsoring Party may continue to dose subjects enrolled in the terminated Combined Therapy Study through completion of the Protocol if dosing is required by the applicable Regulatory Authority(ies) and/or Applicable Law(s). Any such wind-down activities will include the return or destruction of all of the Other Party's Compound provided by the Other Party, and not consumed in the applicable Combined Therapy Study. If applicable, upon termination of this Agreement, the Parties shall remain responsible pursuant to the terms of this Agreement for any expenses incurred that are associated with terminating any ongoing clinical trial work and/or result from such ongoing activities under this Agreement solely to the extent such activities are deemed necessary by the Company (after discussion by the Parties) based on reasonable medical judgment to protect the health of subjects participating in each Combined Therapy Study.

11.5 Survival. The following Articles and Sections of this Agreement and all definitions relating thereto shall survive any expiration or termination of this Agreement for any reason: Article 5, Article 6, Article 7, Article 8, Article 9, Article 10, Article 12, Section 11.4, and this Section 11.5.

Article 12
Miscellaneous

12.1 Entire Agreement. The Parties acknowledge that this Agreement shall govern all activities of the Parties with respect to each Combined Therapy Study from the Effective Date forward. This Agreement, including the Exhibits hereto, together with the Protocol, Supply and Quality Documentation and the Pharmacovigilance Agreement, sets forth the complete, final and exclusive agreement between the Parties concerning the subject matter hereof and supersedes all prior agreements and understandings between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to such subject matter other than as are set forth in this Agreement. All Exhibits attached hereto are incorporated herein as part of this Agreement.

12.2 Governing Law. This Agreement shall be governed and construed in accordance with the internal laws of the State of New York, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

12.3 Dispute Resolution

(a) In the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of this Agreement (each a "***Dispute***"), other than [***], the Parties shall refer such Dispute promptly to the Alliance Managers for resolution. If the Alliance Managers are unable to resolve such Dispute within ten (10) calendar days after a matter has been presented to them, then upon the request of either Party by written notice, the Parties shall refer such Dispute to the Executive Officers. This Agreement shall remain in effect during the pendency of any such Dispute. In the event that no resolution is made by the Executive Officers in good faith negotiations within thirty (30) calendar days after such referral to them, then, if such Dispute constitutes an Arbitration Matter, such Dispute shall be resolved through arbitration in accordance with the remainder of this Section 12.3; *provided* that either Party shall have the right to seek an injunction or other equitable relief in accordance with Section 12.4, and with respect to any Publication Dispute, the specific dispute resolution processes contained in Section 8.5(b) will apply.

(b) If a Dispute that constitutes an Arbitration Matter remains unresolved after escalation to the Executive Officers as described above, either Party may refer the matter to arbitration as described herein. Any arbitration under this Agreement shall be conducted under the auspices of the American Arbitration Association by a panel of three (3) arbitrators pursuant to that organization's Commercial Arbitration Rules then in effect; *provided* that the Parties hereby agree that the time schedule for the appointment of arbitrators and the time schedule for submission of the statement of defense shall follow the American Arbitration Association Arbitration Rules. The fees and expenses of the arbitrators shall be borne in equal shares by the Parties. Each Party shall bear the fees and expenses of its legal representation in the arbitration. The arbitral tribunal shall not reallocate either the fees and expenses of the arbitrators or of the Parties' legal representation. The arbitration shall be held in New York, New York, USA, which shall be the seat of the arbitration. The language of the arbitration shall be English.

12.4 Injunctive Relief. Notwithstanding anything herein to the contrary, a Party may seek an injunction or other injunctive relief from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss or damage on a provisional basis. For the avoidance of doubt, if either Party (a) discloses Confidential Information of the other Party other than as permitted under Article 8, (b) uses (in the case of the Company) the BMS Compound or BMS Technology or (in the case of BMS) either or both of the Company Compounds or Company Technology in any manner other than as expressly permitted under this Agreement or (c) otherwise is in material breach of this Agreement and such material breach could cause immediate harm to the value of either or both of the Company Compounds (by the Company) or the BMS Compound (by BMS), the other Party shall have the right to seek an injunction or other equitable relief precluding the other Party from continuing its activities related to the Combined Therapy Study without waiting for the conclusion of the dispute resolution procedures under Section 12.3.

12.5 Force Majeure. The Parties shall be excused from the performance of their obligations under this Agreement (other than the payment of monies owed to the other Party) to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean acts of God, strikes or other concerted acts of workers, civil disturbances, fires, earthquakes, acts of terrorism, floods, explosions, riots, war, rebellion, sabotage or failure or default of public utilities or common carriers or similar conditions beyond the control of the Parties.

12.6 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if such notice is timely and is: (a) mailed by first class certified or registered mail, postage prepaid, return receipt requested, (b) sent by express delivery service, or (c) personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For the Company: BioAtla, Inc.
11085 Torreyana Road
San Diego, California 92121
Attention: Chief Executive Officer

With a copy to: Orrick Herrington & Sutcliffe LLP
Columbia Center
1152 15th Street, N.W.
Washington, D.C. 20005-1706
United States
Attn: David E. Schulman

For BMS: Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: Vice President, Business Development, Oncology

With a copy to: Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543-4000
Attention: Senior Vice President & Associate General Counsel, Transactions

Any such communication shall be deemed to have been received when delivered. It is understood and agreed that this Section 12.6 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

12.7 No Waiver; Modifications. It is agreed that no waiver by a Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

12.8 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

12.9 Independent Contractors. The Parties are independent contractors of each other, and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall be the agent of the other or have any authority to act for, or on behalf of, the other Party in any matter.

12.10 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent (a) to an Affiliate, (b) to a Third Party that merges with, consolidates with or acquires substantially all of the assets or voting control of the assigning Party or (c) to a Third Party that acquires all the rights to either or both of the Company Compounds, in the case of the Company, or the BMS Compound, in the case of BMS. Any permitted successor or assignee of rights or obligations pursuant to clause (b) or (c) above shall, in a writing to the other Party, expressly assume performance of such rights or obligations. Any assignment or attempted assignment by any Party in violation of the terms of this Section 12.10 shall be null and void and of no legal effect.

12.11 Change of Control. The rights to Patent Rights and other Technology Controlled by a Third Party which participates in a Change of Control involving a Party, which rights to such Patent Rights or other Technology were Controlled by such Third Party immediately prior to such Change of Control, shall be automatically excluded from this Agreement.

12.12 Headings. The captions to the several Sections and Articles hereof are not a part of this Agreement but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

12.13 Counterparts; Electronic Signatures. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by facsimile or electronic (e.g., .pdf) signatures and such signatures shall be deemed to bind each Party hereto as if they were original signature. The Parties (a) are agreeing that each may use electronic signatures, and (b) by doing so agree to being subject to the provisions of the U.S. E-SIGN Act (i.e., the Electronic Signatures in Global and National Commerce Act (enacted June 30, 2000 and codified at 15 U.S.C. § 7001 et seq.)).

12.14 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of a Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

12.15 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in order to perfect any license, assignment or other transfer or any properties or rights under, or pursuant, to this Agreement.

12.16 No Benefit to Third Parties. The representations, warranties and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other parties.

12.17 Other Clinical Trials; Non-Exclusive Relationship

(a) Except for the Combined Therapy Studies, each clinical trial for the BMS Compound and the Company Compounds, alone or in combination with other pharmaceutical agents, is independently conducted and shall not be subject to this Agreement.

(b) Subject to and without limiting the other terms and conditions of this Agreement, nothing in the Agreement shall prohibit [***].

12.18 Construction. Except as otherwise explicitly specified to the contrary, (a) references to a Section, Article, Exhibit or Schedule means a Section or Article of, or Exhibit or Schedule to, this Agreement and all subsections thereof, unless another agreement is specified, (b) references to a particular statute or regulation include all rules and regulations promulgated thereunder and any successor statute, rules or regulations then in effect, in each case including the then-current amendments thereto, (c) words in the singular or plural form include the plural and singular form, respectively, (d) the terms "including," "include(s)," "such as," and "for example" used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation," (e) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement, and (f) the word "or" is used in the inclusive sense that is typically associated with the phrase "and/or." No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

IN WITNESS WHEREOF, the Parties hereto, intending to be legally bound hereby, have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

BRISTOL-MYERS SQUIBB COMPANY		**BIOATLA, INC.**	
By:	/s/ Jonathan Cheng	By:	/s/ Scott A. Smith
Name:	Jonathan Cheng	Name:	Scott A. Smith
Title:	SVP & Head of Oncology Department	Title:	President

Exhibit Index

Exhibit A: Study Plan for the Initial Studies

Exhibit B: Initial Press Release

Exhibit C: Form of Study Plan

Schedule 2.1(c) Study Site Territories

EXHIBIT A
STUDY PLAN FOR THE INITIAL STUDIES
[***]

EXHIBIT B
INITIAL PRESS RELEASE
[***]

EXHIBIT C
FORM OF STUDY PLAN
[***]

SCHEDULE 2.1(c)
STUDY SITE TERRITORIES

[***]

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jay M. Short, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioAtla, Inc.;

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

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

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

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: November 4, 2022

By: /s/ Jay M. Short, Ph.D.
Jay M. Short, Ph.D.
Chief Executive Officer and Director

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard A. Waldron, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioAtla, Inc.;

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

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

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

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: November 4, 2022

By: /s/ Richard A. Waldron
Richard A. Waldron
Chief Financial Officer
(Principal Financial and Accounting 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 of BioAtla, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my 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 result of operations of the Company.

Date: November 4, 2022

By: /s/ Jay M. Short, Ph.D.
Jay M. Short, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 4, 2022

By: /s/ Richard A. Waldron
Richard A. Waldron
Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.