

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 **June 30, 2021**

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
(State or other jurisdiction of
incorporation or organization)
11085 Torreyana Road, San Diego, California
(Address of principal executive offices)

85-1922320
(I.R.S. Employer
Identification No.)
92121
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 August 13, 2021, the number of shares of the registrant's common stock outstanding was 32,315,301 and the number of shares of the registrant's Class B common stock outstanding was 1,492,059.

BIOATLA, INC.
Quarterly Report on Form 10-Q

Table of Contents

	<u>Page</u>
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements:	1
Condensed Consolidated Balance Sheets as of June 30, 2021 (unaudited) and December 31, 2020	1
Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited) for the three and six months ended June 30, 2021 and 2020	2
Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the three and six months ended June 30, 2021 and 2020	3
Condensed Consolidated Statements of Cash Flows (unaudited) for the six months ended June 30, 2021 and 2020	4
Notes to Condensed Consolidated Financial Statements (unaudited)	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3. Quantitative and Qualitative Disclosures About Market Risk	24
Item 4. Controls and Procedures	24
PART II. OTHER INFORMATION	25
Item 1. Legal Proceedings	25
Item 1A. Risk Factors	25
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	69
Item 3. Defaults Upon Senior Securities	69
Item 4. Mine Safety Disclosures	69
Item 5. Other Information	69
Item 6. Exhibits	70
SIGNATURES	71

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	June 30, 2021 <u>(unaudited)</u>	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 207,609	\$ 238,605
Prepaid expenses and other current assets	4,722	2,076
Total current assets	<u>212,331</u>	<u>240,681</u>
Property and equipment, net	4,223	4,102
Other assets	154	154
Total assets	<u>\$ 216,708</u>	<u>\$ 244,937</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 15,898	\$ 12,068
Current portion of deferred rent	452	387
Current portion of deferred revenue	19,806	19,806
Total current liabilities	<u>36,156</u>	<u>32,261</u>
Long-term accrued interest	8	5
Deferred rent, less current portion	1,839	2,015
Other debt	682	682
Total liabilities	<u>38,685</u>	<u>34,963</u>
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 200,000,000 shares authorized at June 30, 2021 and December 31, 2020; 0 shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, \$0.0001 par value; 350,000,000 shares authorized at June 30, 2021 and December 31, 2020; 32,315,301 and 32,171,560 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	3	3
Class B common stock, \$0.0001 par value; 15,368,569 shares authorized at June 30, 2021 and December 31, 2020; 1,492,059 shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	318,019	300,888
Accumulated deficit	(139,999)	(90,917)
Total stockholders' equity	<u>178,023</u>	<u>209,974</u>
Total liabilities and stockholders' equity	<u>\$ 216,708</u>	<u>\$ 244,937</u>

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration and other revenue	\$ 250	\$ 190	\$ 250	\$ 279
Operating expenses:				
Research and development expense	14,850	2,923	25,273	4,584
General and administrative expense	15,860	1,787	24,234	1,324
Total operating expenses	<u>30,710</u>	<u>4,710</u>	<u>49,507</u>	<u>5,908</u>
Loss from operations	(30,460)	(4,520)	(49,257)	(5,629)
Other income (expense):				
Interest income	80	1	178	6
Interest expense (includes related party amounts of \$0 for the three and six months ended June 30, 2021 and \$79 and \$138 for the three and six months ended June 30, 2020, respectively)	(1)	(754)	(3)	(1,301)
Change in fair value of derivative liability	—	(775)	—	(728)
Extinguishment of convertible debt	—	(174)	—	(174)
Total other income (expense)	<u>79</u>	<u>(1,702)</u>	<u>175</u>	<u>(2,197)</u>
Consolidated net loss and comprehensive loss	<u>\$ (30,381)</u>	<u>\$ (6,222)</u>	<u>\$ (49,082)</u>	<u>\$ (7,826)</u>
Net loss per common share, basic and diluted ⁽¹⁾	<u>\$ (0.90)</u>		<u>\$ (1.46)</u>	
Weighted-average shares of common stock outstanding, basic and diluted ⁽¹⁾	<u>33,678,893</u>		<u>33,671,298</u>	

⁽¹⁾ For the three and six months ended June 30, 2020, the Company determined that the attribution of pre-Corporate Reorganization net losses based on the post-Corporate Reorganization capital structure would not meaningfully represent the economic rights of the unit holders. As a result, the Company presents net loss per share information only for the period subsequent to the Corporate Reorganization. (see Note 1).

See accompanying notes.

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

	Three Months Ended June 30, 2021						
	Common Stock		Class B Common Stock		Additiona l Paid-in	Accumulate d	Total Stockholde rs'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at March 31, 2021	32,171,560	\$ 3	1,492,059	\$ —	\$ 305,531	\$ (109,618)	\$ 195,916
Stock-based compensation expense	—	—	—	—	12,298	—	12,298
Issuance of common stock under equity incentive plans	138,461	—	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	5,280	—	—	—	190	—	190
Net loss	—	—	—	—	—	(30,381)	(30,381)
Balance at June 30, 2021	32,315,301	\$ 3	1,492,059	\$ —	\$ 318,019	\$ (139,999)	\$ 178,023

	Six Months Ended June 30, 2021						
	Common Stock		Class B Common Stock		Additional Paid-in	Accumulate d	Total Stockholde rs'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2020	32,171,560	\$ 3	1,492,059	\$ —	\$ 300,888	\$ (90,917)	\$ 209,974
Stock-based compensation expense	—	—	—	—	16,941	—	16,941
Issuance of common stock under equity incentive plans	138,461	—	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	5,280	—	—	—	190	—	190
Net loss	—	—	—	—	—	(49,082)	(49,082)
Balance at June 30, 2021	32,315,301	\$ 3	1,492,059	\$ —	\$ 318,019	\$ (139,999)	\$ 178,023

See accompanying notes.

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

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities		
Net loss	\$ (49,082)	\$ (7,826)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	636	431
Loss on disposal of property and equipment	4	—
Change in fair value of derivative liability	—	728
Change in fair value of profits interest liability	—	(7,601)
Loss on extinguishment of debt	—	174
Stock-based compensation	16,941	—
Non-cash interest	—	489
Accrued interest	3	813
Deferred rent	(111)	(51)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,646)	389
Accounts payable and accrued expenses	5,716	5,867
Deferred revenue	—	(279)
Net cash used in operating activities	(28,539)	(6,866)
Cash flows from investing activities		
Purchases of property and equipment	(736)	(86)
Net cash used in investing activities	(736)	(86)
Cash flows from financing activities		
Proceeds from issuance of convertible debt	—	2,750
Proceeds from issuance of PPP loan	—	682
Payment of initial public offering costs	(1,911)	—
Proceeds from issuance of common stock under Employee Stock Purchase Plan	190	—
Net cash provided by (used in) financing activities	(1,721)	3,432
Net decrease in cash and cash equivalents	(30,996)	(3,520)
Cash and cash equivalents, beginning of period	238,605	3,704
Cash and cash equivalents, end of period	\$ 207,609	\$ 184
Supplemental disclosure of non-cash investing and financing activities		
Unpaid deferred financing costs	\$ —	\$ 95
Property and equipment additions included in accounts payable and accrued expenses	\$ 42	\$ 89

See accompanying notes.

BioAtla, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization

BioAtla, LLC was formed in Delaware in March 2007 and converted to a Delaware corporation in July 2020 as part of the Corporate Reorganization defined and described below, 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.

Corporate Reorganization and Series D Financing

In July 2020, BioAtla, LLC completed a series of transactions (the "Corporate Reorganization") in connection with the conversion from a limited liability company into a Delaware corporation, the spin-off of Himalaya Therapeutics SEZC, and the completion of a Series D convertible preferred stock financing. The Corporate Reorganization involved the formation of Himalaya Parent LLC as a wholly owned subsidiary of BioAtla, LLC and the formation of BioAtla MergerSub LLC, as a wholly owned subsidiary of Himalaya Parent LLC. Under the Agreement and Plan of Merger (the "Merger Agreement"), BioAtla, LLC was merged into and with BioAtla MergerSub LLC, with BioAtla, LLC surviving, and the members of BioAtla, LLC immediately prior to the effective time of the Merger Agreement received membership interests, on a one-for-one basis, of Himalaya Parent LLC as consideration, and the then-outstanding warrants to purchase equity of BioAtla, LLC were converted into warrants to purchase common shares of common stock of BioAtla, Inc. (see Note 6). The Himalaya Parent LLC operating agreement provided identical equity rights for the then outstanding units of BioAtla, LLC. In addition: (i) the membership interests of BioAtla, LLC held by Himalaya Parent LLC were exchanged for 6,220,050 shares of BioAtla, Inc. common stock, (ii) BioAtla, Inc. issued an aggregate of 59,164,808 shares of Series D convertible preferred stock to Himalaya Parent LLC and Himalaya Parent LLC issued an aggregate of 59,164,808 Class D units to the holders of convertible notes of BioAtla, LLC in connection with the conversion of their convertible notes into Class D units of Himalaya Parent LLC (see Note 4), (iii) BioAtla, LLC distributed to Himalaya Parent LLC its equity interests in Himalaya Therapeutics SEZC, a then majority-owned subsidiary which is engaged in the development of a set of antibodies in the field of oncology primarily in Greater China, (iv) Himalaya Parent LLC assumed the profits interest liability of BioAtla, LLC (see Note 7) and (v) BioAtla, LLC converted into a Delaware corporation pursuant to a statutory conversion and changed its name to BioAtla, Inc. Following the Corporate Reorganization, Himalaya Parent LLC owned 59,164,808 shares of BioAtla, Inc. Series D convertible preferred stock and 6,220,050 shares of BioAtla, Inc. common stock, all of which were subsequently distributed (the "Distribution") to the members of Himalaya Parent LLC. As a result of the sale of 140,626,711 shares of Series D convertible preferred stock to new investors in July 2020 (see Note 6), BioAtla, Inc. was not controlled by Himalaya Parent LLC and BioAtla, Inc. does not control Himalaya Parent LLC subsequent to the distribution (see further discussion in "Principles of consolidation and deconsolidation" below). All pre-Corporate Reorganization operations, employees, property, assets and obligations of BioAtla, LLC (exclusive of the profits interest liability and Himalaya Therapeutics SEZC now held by Himalaya Parent LLC) are held by BioAtla, Inc. Shares of Series D convertible preferred stock were subsequently converted into common stock as part of the Company's initial public offering ("IPO") in December 2020.

Principles of Consolidation and Deconsolidation

Prior to the Corporate Reorganization in July 2020, 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 and subsequent to the Distribution as defined and described above, Himalaya Parent LLC does not control, is not under common control with, and is not consolidated by BioAtla, Inc. and BioAtla, Inc. is a single legal entity with no consolidated variable interest entities ("VIEs") or subsidiaries.

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 June 30, 2021, the Company had an accumulated deficit of \$140.0 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.

Unaudited Interim Financial Information

The unaudited condensed consolidated financial statements as of June 30, 2021, and for the three and six months ended June 30, 2021 and 2020, 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, 2020, included in its Annual Report on Form 10-K filed with the SEC on March 24, 2021.

Use of Estimates

The preparation of the Company's 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 consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to revenue recognition, accruals for research and development costs, equity-based compensation and fair value measurements. 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.

Income Taxes

In March 2021, the American Rescue Plan (H.R. 1319) was signed into law. This legislation extends and enhances a number of current-law tax incentives for businesses, but also expands the definition of a "covered employee" as defined by Section 162(m)(1) of the Internal Revenue Code. The corporate tax provisions included within the bill are not expected to have a material impact on the Company.

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.

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 common stock warrants, RSUs, and common stock options outstanding under the Company's stock option plan.

For the three and six months ended June 30, 2020, the Company determined that the attribution of pre-Corporate Reorganization net loss based on the post-Corporate Reorganization capital structure would not meaningfully represent the economic rights of the unit holders. As a result, the Company presents net loss per share information only for the period subsequent to the Corporate Reorganization.

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):

	June 30, 2021
Common stock warrants	717,674
Common stock options	850,149
Restricted stock units	1,781,576
Total	<u>3,349,399</u>

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use model and requires a lessee to recognize on the balance sheet a right-of-use asset and corresponding lease liability for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022 and early adoption is permitted. While management is currently assessing the impact this new standard will have, the expected primary impact to its consolidated financial position upon adoption will be the recognition, on a discounted basis, of its minimum commitments under noncancelable operating leases on its consolidated balance sheets resulting in the recording of right of use assets and lease liabilities. The Company's current minimum commitments under its noncancelable operating leases are disclosed in Note 5.

2. Balance Sheet Details

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

	June 30, 2021	December 31, 2020
Prepaid research and development	\$ 2,915	\$ 2,004
Prepaid insurance	1,461	—
Other prepaid expenses and current assets	346	72
Total	<u>\$ 4,722</u>	<u>\$ 2,076</u>

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

	Useful life (years)	June 30, 2021	December 31, 2020
Furniture, fixtures and office equipment	3 - 7	\$ 1,933	\$ 1,719
Laboratory equipment	5	2,197	1,790
Leasehold improvements	2 - 3	3,687	3,663
Construction in progress		102	—
		<u>7,919</u>	<u>7,172</u>
Less accumulated depreciation and amortization		(3,696)	(3,070)
Total		<u>\$ 4,223</u>	<u>\$ 4,102</u>

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

	June 30, 2021	December 31, 2020
Accounts payable	\$ 1,283	\$ 2,456
Accrued compensation	2,240	2,804
Accrued research and development	11,743	4,852
Accrued equity issuance costs	—	1,143
Other accrued expenses	632	813
Total	<u>\$ 15,898</u>	<u>\$ 12,068</u>

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 June 30, 2021 and December 31, 2020, 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. Convertible and Other Debt

The Company issued convertible promissory notes between December 2015 and May 2020 totaling \$21.8 million, of which \$2.0 million was with related parties. The convertible promissory notes accrued interest at 8% per annum with maturity dates of five years after issuance. The convertible promissory notes were settled in connection with the Company's Series D financing in July 2020. As of June 30, 2021, the Company had \$0.7 million outstanding under a promissory note issued pursuant to the Paycheck Protection Program ("PPP") of the CARES Act. On July 2, 2021, the Company received notice from its lender that the U.S. Small Business Administration ("SBA") had approved the Company's application for forgiveness and that there was no remaining balance on the PPP Loan. The Company expects to record the forgiveness as other income in July 2021. For the three and six months ended June 30, 2021, the Company recognized interest expense related to its outstanding debt of \$1,000 and \$3,000, respectively. For the three and six months ended June 30, 2020, the Company recognized interest expense related to its outstanding debt of \$0.8 million and \$1.3 million, respectively.

5. Commitments and Contingencies

Operating Lease

In June 2017, as amended in January 2019, the Company entered into a non-cancellable operating lease for its corporate headquarters and laboratory space in San Diego, California. The lease commenced in January 2018, the period the Company gained access to the leased space and began recognizing rent expense. The lease expires in July 2025 and the Company has an option to extend the term of the lease for an additional five years. The lease includes certain rent abatement, rent escalations, tenant improvement allowances and additional charges for common area maintenance and other costs. Rent expense for the three and six months ended June 30, 2021 was \$0.4 million and \$0.8 million, respectively. Rent expense for the three and six months ended June 30, 2020 was \$0.5 million and \$0.9 million, respectively.

Expected future minimum payments under the non-cancelable operating lease as of June 30, 2021 are as follows (in thousands):

<u>Years ending December 31:</u>	<u>Operating Lease</u>
2021 (6 months)	\$ 741
2022	1,555
2023	1,636
2024	1,685
Thereafter	845
	<u>\$ 6,462</u>

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.

6. Stockholders'/Members' Equity (Deficit)

The statement of members' deficit for the three months ended June 30, 2020 is as follows (in thousands, except unit amounts):

	Class C Preferred Units		Class A Units		Additional Paid-in Capital	Accumulated Deficit	Noncontrolling Interest	Total Members' Deficit
	Units	Amount	Units	Amount				
Balance at March 31, 2020	23,968,178	\$ 89,345	54,600,000	\$ 750	\$ 2,295	\$ (149,958)	\$ (47)	\$ (57,615)
Net loss	—	—	—	—	—	(6,222)	—	(6,222)
Balance at June 30, 2020	<u>23,968,178</u>	<u>\$ 89,345</u>	<u>54,600,000</u>	<u>\$ 750</u>	<u>\$ 2,295</u>	<u>\$ (156,180)</u>	<u>\$ (47)</u>	<u>\$ (63,837)</u>

The statement of members' deficit for the six months ended June 30, 2020 is as follows (in thousands, except unit amounts):

	Class C Preferred Units		Class A Units		Additional Paid-in Capital	Accumulated Deficit	Noncontrolling Interest	Total Members' Deficit
	Units	Amount	Units	Amount				
Balance at December 31, 2019	23,968,178	\$ 89,345	54,600,000	\$ 750	\$ 2,295	\$ (148,354)	\$ (47)	\$ (56,011)
Net loss	—	—	—	—	—	(7,826)	—	(7,826)
Balance at June 30, 2020	<u>23,968,178</u>	<u>\$ 89,345</u>	<u>54,600,000</u>	<u>\$ 750</u>	<u>\$ 2,295</u>	<u>\$ (156,180)</u>	<u>\$ (47)</u>	<u>\$ (63,837)</u>

Initial Public Offering and Related Transactions

In December 2020, the Company completed its IPO selling 12,075,000 shares of its common stock at \$18.00 per share. Proceeds from the Company's IPO, net of underwriting discounts and commissions and other offering costs, were \$198.3 million. In connection with the IPO, all 199,791,519 shares of convertible preferred stock outstanding at the time of the IPO converted into 13,876,510 shares of the Company's common stock and 1,492,059 shares of the Company's Class B common stock.

2020 Equity Incentive Plan

On October 29, 2020, the Company's board of directors approved the adoption of the BioAtla, Inc. 2020 Equity Incentive Plan (the "2020 Plan") and approved certain amendments to the 2020 Plan in December 2020. The Company's stockholders approved the 2020 Plan, as amended, in December 2020. Under the 2020 Plan, the Company may grant awards of common stock 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 June 30, 2021 and December 31, 2020, the total number of common shares authorized for issuance under the 2020 Plan was 6,226,540 and 4,939,678, 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.

There was no stock-based compensation expense reported for the three and six months ended June 30, 2020 as the 2020 Plan was not yet adopted. Stock-based compensation expense for the three and six months ended June 30, 2021 has been reported in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended June 30, 2021	Six Months Ended June 30, 2021
Research and development	\$ 1,154	\$ 2,109
General and administrative	11,144	14,832
Total	\$ 12,298	\$ 16,941

Restricted Stock Units

The following table summarizes RSU activity under the 2020 Plan for the six months ended June 30, 2021:

	Number of Shares	Weighted - Average Grant Date Fair Value
Outstanding at December 31, 2020	1,920,037	\$ 18.00
Vested	(138,461)	\$ 18.00
Outstanding at June 30, 2021	1,781,576	\$ 18.00

As of June 30, 2021, total unrecognized stock-based compensation expense for RSUs was \$23.0 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.7 years. During the six months ended June 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 six months ended June 30, 2021 (in thousands, except share and per share data and years):

	Number of Options	Weighted - Average Exercise Price Per Share	Weighted - Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at December 31, 2020	615,106	\$ 18.00	9.95	\$ 9,848
Granted	235,043	\$ 44.57		
Balance at June 30, 2021	850,149	\$ 25.35	9.48	\$ 15,199
Vested and expected to vest at June 30, 2021	850,149	\$ 25.35	9.48	\$ 15,199
Exercisable at June 30, 2021	7,747	\$ 18.00	0.16	\$ 189

As of June 30, 2021, total unrecognized stock-based compensation cost for unvested common stock options was \$12.6 million, which is expected to be recognized over a remaining weighted-average period of approximately 3.4 years. The weighted-average grant date fair value of stock options granted during the six months ended June 30, 2021 was \$28.91 per share. During the six months ended June 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:

	Six Months Ended June 30, 2021
Expected volatility	74.76 %
Risk-free interest rate	0.98 %
Expected dividend yield	0.0 %
Expected term	5.94 years

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

In December 2020, the Company's board of directors and stockholders approved the BioAtla, Inc. Employee Stock Purchase Plan (the "ESPP"). The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. As of June 30, 2021 and December 31, 2020, a total of 833,993 shares and 464,829 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's first ESPP purchase transaction occurred on June 30, 2021. During the six months ended June 30, 2021, the Company issued 5,280 shares of common stock under the ESPP. As of June 30, 2021, 828,713 shares of common stock remained available for issuance under the ESPP. Stock-based compensation expense related to the ESPP for the three and six months ended June 30, 2021 was immaterial.

Common Stock Warrants

Upon adoption of ASU No. 2018-07 on October 1, 2020, the measurement date of the warrants described below became fixed in accordance with the guidance, and such fair value was nominal since the warrants were deeply out-of-the-money. As of June 30, 2021 all the common stock warrants below are exercisable and expire as follows:

Outstanding and Exercisable		Exercise Price per Share	Expiration Date
566,586	\$	88.25	December 17, 2021
151,088	\$	132.37	March 12, 2022
<u>717,674</u>			

Common Stock Reserved for Future Issuance

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

	June 30, 2021	December 31, 2020
Warrants for the purchase of common stock	717,674	717,674
Common stock options and restricted stock units issued and outstanding	2,631,725	2,535,143
Awards available for future issuance under the 2020 Plan	3,456,354	2,404,535
Awards available for future issuance under the ESPP	828,713	464,829
Total common stock reserved for future issuance	<u>7,634,466</u>	<u>6,122,181</u>

7. Profits Interest Incentive Plan

Prior to the Corporate Reorganization in July 2020, the Company maintained a Profits Interest Incentive Plan (the “Plan”) for selected employees, consultants and other service providers. The Class B units generally vested over four years, were subject to continued service requirements, and only provide the participants with benefits (in the form of distributions) if the distributions from BioAtla exceed specified threshold values. Generally, upon termination of services, all unvested Class B units were forfeited to the Company and the Company had the right, but not the obligation, to repurchase the vested Class B units within two years at the termination date fair value. The Class B unit repurchase would be settled in cash, at all times at the option of the Company, and the holder did not have the right to put the Class B units to the Company under any condition. Vested Class B units that are neither repurchased by the Company nor forfeited remained subject to the terms of the Company’s operating agreement. The Class B units were not subject to sale, assignment, transfer, pledge, or allowed to be otherwise encumbered or disposed of without prior written consent of the Company.

The Class B units were liability awards pursuant to authoritative guidance, which required the Company to record a liability based on the fair value of the Class B units as of each reporting period. Through the date of the Corporate Reorganization, the fair value of the liability awards was determined based on the Company’s estimated enterprise value, which was allocated based on a hybrid model that, in addition to the option pricing model, considering the Company’s expected IPO. Under the option pricing method, units were valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each unit class.

The allocation of equity-based compensation for all Class B units is as follows (in thousands):

	Three Months Ended June 30, 2020	Six Months Ended June 30, 2020
Research and development	\$ (837)	\$ (3,360)
General and administrative	(1,061)	(4,241)
Total	<u>\$ (1,898)</u>	<u>\$ (7,601)</u>

8. Collaboration, License and Option Agreements

Global Co-Development and Collaboration Agreement with 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”).

Under the BeiGene Collaboration the Company would co-develop the CAB-CTLA-4 antibody to reach defined early clinical objectives (“POC Milestone”), whereby the Company would perform the development activities (“Development Services”) and BeiGene would reimburse the Company for a portion of the costs incurred by the Company for these Development Services subsequent to the filing of an Investigational New Drug Application (“IND”). Following the POC Milestone, BeiGene would then lead the parties’ joint efforts to develop the product candidate and be responsible for global regulatory filings and commercialization. Subject to the terms of the agreement, BeiGene will hold a co-exclusive license with the Company to develop and manufacture the

product candidate globally and an exclusive license to commercialize the product candidate globally. BeiGene will be responsible for all costs of development, manufacturing and commercialization in China, parts of the Middle East and Asia (excluding Japan), Australia and New Zealand (the “BeiGene Territory”), and the parties would share development and manufacturing costs and commercial profits and losses upon specified terms in the rest of the world that are not part of the BeiGene Territory (the “ROW”).

Subject to earlier termination, the BeiGene Collaboration shall remain in effect, on a country-by-country basis until the earlier of ten years following commercial sale or upon such time that the parties cease pursuing commercialization. Unless terminated early, at the expiration date BeiGene retains all licensing rights in the applicable territories. BeiGene may terminate the BeiGene Collaboration at any time after the one-year anniversary of the agreement subject to 90 days written notice, or any time subject to 45 days’ notice if it is determined that the proof of concept (“POC”) milestone or technological or scientific feasibility will not be achieved. The BeiGene Collaboration also contains customary provisions for termination by either party, including the event of breach of the BeiGene Collaboration, subject to cure.

In 2019, BeiGene paid the Company an upfront non-refundable payment of \$20.0 million and paid the Company \$5.0 million for the reimbursement of manufacturing costs. Under the BeiGene Collaboration, the Company was eligible to receive variable consideration for subsequent development and regulatory milestones globally and commercial milestones in the BeiGene Territory and tiered royalties ranging from the mid-single digits to the mid-double digits based on net sales in the BeiGene Territory.

The Company concluded that the BeiGene Collaboration is a contract with a customer and applied relevant guidance from Topic 606 through reaching the POC milestone as the licenses to intellectual property granted to BeiGene and the obligation to perform research and development services are outputs of the Company’s ongoing activities.

The Company identified material promises in the BeiGene Collaboration through POC milestone, consisting of the licenses described above and the Development Services. It was determined that the licenses are not distinct from the development services resulting in a single performance obligation.

In accordance with Topic 606, the Company determined the transaction price of the agreement is limited to the \$25.0 million received, and excluded the variable consideration of expense reimbursements, milestone payments and royalties as they are fully constrained. The expense reimbursements were included in the transaction price in the reporting period the Company concluded it was probable that inclusion of such amounts in the transaction price would not result in a significant reversal in revenue recognized. As part of the Company’s evaluation of the milestone constraints, the Company determined the achievement of such milestones are contingent upon success in future developments, regulatory approvals and commercial activities which are not within its control and are uncertain at this stage. Variable consideration related to royalties will be recognized when the related sales occur.

Under the terms of the Amended BeiGene Collaboration, BeiGene is generally responsible for developing BA3071 and is responsible for global regulatory filings and commercialization. Subject to the terms of the Amended BeiGene Collaboration, BeiGene holds an exclusive license with the Company to develop and manufacture the BA3071 candidate globally, and BeiGene is responsible for all costs of development, manufacturing and commercialization globally. The Amended BeiGene Collaboration provides that the Company is eligible to receive tiered royalties, ranging from the high-single digits to the low twenties, on sales worldwide, up to \$225.5 million in subsequent development and regulatory milestone payments globally and commercial milestones in the BeiGene territory (reduced from \$249 million under the BeiGene Collaboration), and a \$5.0 million milestone payment upon the completion of the Company’s amended performance obligations, including the transfer of the master cell bank for BA3071 and other know-how.

Under the Amended BeiGene Collaboration, the Company’s amended performance obligation is satisfied at a point in time determined to be when BeiGene has received the know-how and master cell bank for BA3071. Until then BeiGene cannot benefit from the ability to further develop and manufacture the BA3071 candidate. Under the original collaboration agreement, the Company recognized revenue over time using an input method based on actual costs incurred compared to estimated total costs expected to be incurred to fulfill its performance obligation to perform development services.

For the three and six months ended June 30, 2021, the Company did not recognize any revenue related to the collaboration agreement with BeiGene. As of June 30, 2021 and December 31, 2020, the Company had \$19.8 million of related deferred revenue which was classified as current. The deferred revenue is expected to be earned upon transfer of the know-how and master cell bank within the next twelve months.

Service Contracts

Prior to developing its own programs, the Company entered into various fixed price research services contracts. In connection with these 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 three and six months ended June 30, 2021 related to the achievement of a clinical milestone on a fixed price service contract.

9. Related Party Transactions

Biotech Investment Group, LLC

Prior to the Corporate Reorganization, Biotech Investment Group, LLC (“BIG”), was a principal owner, related party of the Company and affiliated with Biotech Investment Group II LLC (“BIG II”). Subsequent to the Corporate Reorganization, BIG is no longer a principal owner and, as a result, neither BIG nor its affiliates are related parties of the Company.

Biotech Investment Group II LLC

For the three and six months ended June 30, 2020, the Company recognized interest expense (including amortization of debt discounts) of \$20,000 and \$40,000, respectively, related to an outstanding convertible promissory note payable to BIG II. The convertible promissory note payable to BIG II was settled in connection with the Corporate Reorganization in July 2020.

Dr. Jay Short and Carolyn Anderson Short

Convertible Promissory Notes

For the three and six months ended June 30, 2020, the Company recognized interest expense (including amortization of debt discounts) of \$59,000 and \$98,000 respectively, related to outstanding convertible promissory notes payable to Dr. Jay Short and Carolyn Anderson Short. The convertible promissory notes payable to Dr. Jay Short and Carolyn Anderson Short were settled in connection with the Corporate Reorganization in July 2020.

Transition Agreement

On March 18, 2021, the Company and Carolyn Anderson Short, its co-founder and former Chief of Intellectual Property & Strategy, mutually agreed that Ms. Short would depart the Company on May 31, 2021 following an agreed upon transition period. The Transition Agreement provides for the following severance benefits in exchange for a release of claims by Ms. Short: (i) a lump sum payment equal to eighteen (18) months of Ms. Short’s current base salary, (ii) a payment at her targeted bonus rate for 2021, pro-rated to the separation date, and (iii) accelerated full 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. For the three and six months ended June 30, 2021, the Company recognized \$0.8 million 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 \$8.4 million and \$9.4 million related to the modified equity awards for the three and six months ended June 30, 2021, respectively. No unrecognized stock-based compensation remained as of June 30, 2021.

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 June 30, 2021 and December 31, 2020, 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 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, 2020 included in the Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or the SEC, on March 24, 2021. 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 phase 2 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, 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 BA3011 and BA3021, 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 do not have any products approved for sale, and we have not generated any revenue from product sales.

In July 2020, BioAtla, LLC completed a series of transactions, or the Corporate Reorganization, in connection with which it converted from a limited liability company into a Delaware corporation, spun-off Himalaya Therapeutics SEZC, and completed a Series D convertible preferred stock financing. Following the Corporate Reorganization, BioAtla, Inc. continued to hold all operations, employees, property and assets of BioAtla, LLC (excluding Himalaya Therapeutics SEZC) and assumed all of the obligations of BioAtla, LLC (exclusive of the profits interest liability related to awards granted under BioAtla, LLC’s profits interest plan). In addition, following the Corporate Reorganization, BioAtla, Inc. is a single legal entity with no consolidated variable interest entities, or VIEs, or subsidiaries. The condensed consolidated financial statements discussed in this section and included in Item 1 of this Quarterly Report on Form 10-Q are those of BioAtla, LLC and its consolidated subsidiaries prior to the Corporate Reorganization and those of BioAtla, Inc. subsequent to the Corporate Reorganization.

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 loss was \$30.4 million and \$49.1 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2021, we had an accumulated deficit of \$140.0 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, 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.

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

- advance the clinical development of BA3011;
- advance the clinical development of BA3021;
- 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.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other administrative and professional services expenses that we did not incur as a private company.

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.

Through the date of our initial public offering, or IPO, in December 2020, we had funded our operations primarily through the receipt of \$71.0 million from our collaboration agreements, \$27.6 million from the issuance of convertible debt and \$138.3 million from the issuance of equity securities. In December 2020, we completed our IPO in which we sold 12,075,000 shares of our common stock at the IPO price to the public of \$18.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares, for aggregate cash proceeds of \$217.4 million. We incurred \$19.0 million of issuance costs in connection with our IPO. Upon the closing of our IPO, all outstanding shares of our convertible preferred stock converted into 13,876,510 shares of our common stock and 1,492,059 shares of our Class B common stock. As of June 30, 2021, our cash and cash equivalents totaled approximately \$207.6 million. Based on our current operating plan, our current cash and cash equivalents are expected to be sufficient to fund our ongoing operations at least through the end of 2022. 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

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 caused by a novel strain of coronavirus as a pandemic, which continues to spread throughout the United States and around the world. 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 only experienced non-material business disruptions, including with respect to any of the clinical trials we are conducting, or impairments of any of our assets as a result of the pandemic. 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, began restricting non-essential travel and temporarily reduced salaries of our employees from March 2020 to July 2020. 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 submitted an application for loan forgiveness in June 2021. We were subsequently notified on July 2, 2021 that the U.S. Small Business Association approved our application for loan forgiveness for the full amount of the PPP Loan outstanding. The PPP loan is discussed further under "—Liquidity and capital resources." 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 April 2019, we entered into a Global Co-Development and Collaboration Agreement with BeiGene, Ltd. which, as amended in December 2019 and October 2020, provides for the development, manufacturing and commercialization of BA3071. Under the terms of our BeiGene collaboration, BeiGene is generally responsible for developing BA3071 and is responsible for global regulatory filings and commercialization. Subject to the terms of the agreement, BeiGene holds an exclusive license with us to develop and manufacture the product candidate globally. BeiGene is responsible for all costs of development, manufacturing and commercialization globally. At the time of execution of the BeiGene collaboration, we received a \$20.0 million upfront payment and in December 2019, we received an additional \$5.0 million for the reimbursement of manufacturing costs. We are eligible to receive up to \$225.5 million in subsequent development and regulatory milestones globally and commercial milestones in the BeiGene territory, together with tiered royalties, ranging from the high-single digits to the low twenties, on sales worldwide. Pursuant to the terms of the October 2020 amendment, we agreed to transfer certain know-how and materials to BeiGene related to the manufacture of BA3071. We are currently in preliminary discussions with BeiGene regarding the allocation of roles and responsibilities under our Global Co-Development and Collaboration Agreement with BeiGene, including with respect to the initiation of the Phase I trial for 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.

Prior to developing our own programs, the Company received revenue from services performed under fixed price service contracts that, in some cases, provided for potential milestone and royalty payments to us.

We recognized \$0.3 million in collaboration revenues for the three and six months ended June 30, 2021 from our legacy service contracts. For the three and six months ended June 30, 2020 we recognized \$0.2 million and \$0.3 million of revenue from our collaboration with BeiGene, 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, including through our relationship with BioDuro, 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 expenses.

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 increase substantially 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. 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 consist primarily of 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, audit and accounting services and insurance costs. Personnel-related expenses consist of salaries, benefits and equity-based compensation. We expect our general and administrative expenses to increase as a result of operating as a public company, including additional costs (i) to comply with the rules and regulations of the SEC and those of The Nasdaq Global Market, (ii) for legal and auditing services, (iii) for additional insurance, (iv) for investor relations activities and (v) for other administrative and professional services. We also expect our intellectual property expenses to increase as we expand our intellectual property portfolio.

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.

Interest Expense

Interest expense consists primarily of interest incurred on our outstanding convertible debt, including coupon interest and the amortization of debt discounts, including those related to beneficial conversion features and embedded derivatives. Our interest expense declined subsequent to the settlement of our outstanding convertible debt in July 2020 and the forgiveness of our PPP loan in July 2021.

Change in Fair Value of Derivative Liability

The convertible promissory notes we issued during 2019 and 2020 contained redemption features which we determined were embedded derivatives to be recognized as liabilities and measured at fair value. At the end of each reporting period, changes in the estimated fair value during the period were recorded as a change in the fair value of derivative liability. The embedded derivative liability was recorded at fair value utilizing an income approach that identified the cash flows using a “with-and without” valuation methodology. The inputs used to determine the estimated fair value of the derivative instrument were based primarily on the probability of an underlying event triggering the embedded derivative occurring and the timing of such event. We will no longer record changes in the fair value of the derivative liability subsequent to the settlement of the derivative liability in connection with the conversion of our outstanding convertible debt in July 2020.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

	Three Months Ended June 30,		Change
	2021	2020	
(in thousands)			
Collaboration revenue	\$ 250	\$ 190	\$ 60
Operating expenses:			
Research and development	14,850	2,923	11,927
General and administrative	15,860	1,787	14,073
Total operating expenses	30,710	4,710	26,000
Loss from operations	(30,460)	(4,520)	(25,940)
Other income (expense):			
Interest income	80	1	79
Interest expense	(1)	(754)	753
Change in fair value of derivative liability	—	(775)	775
Extinguishment of convertible debt	—	(174)	174
Total other income (expense)	79	(1,702)	1,781
Consolidated net loss and comprehensive loss	\$ (30,381)	\$ (6,222)	\$ (24,159)

Collaboration Revenue

Collaboration revenue for the three months ended June 30, 2021 was \$0.3 million and consisted of revenue recognized under our legacy service contracts. There was no revenue recognized under our collaboration with BeiGene during the three months ended June 30, 2021. Collaboration revenue for the three months ended June 30, 2020 was \$0.2 million and consisted of revenue recognized under our collaboration agreement with BeiGene. Under the collaboration agreement with BeiGene, the remaining \$19.8 million of deferred revenue is expected to be earned upon transfer of the know-how and materials to BeiGene related to the manufacture of BA3071.

Research and Development Expense

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

	Three Months Ended June 30,		Change
	2021	2020	
(in thousands)			
External expenses:			
BA3011 (AXL-ADC)	\$ 5,231	\$ 679	\$ 4,552
BA3021 (ROR2-ADC)	4,077	546	3,531
Other CAB Programs	2,046	581	1,465
Total external expenses	11,354	1,806	9,548
Personnel and related	1,659	1,366	293
Equity-based compensation	1,154	(837)	1,991
Facilities and other	683	588	95
Total research and development expenses	\$ 14,850	\$ 2,923	\$ 11,927

Research and development expenses were \$14.9 million and \$2.9 million for the three months ended June 30, 2021 and 2020, respectively. The increase of \$12.0 million was primarily driven by a \$8.1 million increase in external costs due to manufacturing for our clinical candidates and ongoing clinical development for BA3011 and BA3021, a \$1.5 million increase in pre-clinical development for other CAB programs, a \$1.1 million increase in stock-based compensation under our post-IPO equity incentive plans, a \$0.9 million increase in equity-based compensation related to a decrease in the fair value of awards under our profits interest plan during the three months ended June 30, 2020, a \$0.3 million increase in personnel related costs, and a \$0.1 million increase and facility and other related expense.

General and Administrative Expense

General and administrative expenses were \$15.9 million and \$1.8 million for the three months ended June 30, 2021 and 2020, respectively. The increase of \$14.1 million was primarily driven by a \$11.1 million increase in stock-based compensation under our

post-IPO equity incentive plans, a \$1.1 million increase in equity-based compensation related to a decrease in the fair value of awards under our profits interest plan during the three months ended June 30, 2020, a \$0.9 million increase in personnel related expenses as we expanded our administrative functions in support of our development activities and incurred severance benefits related to the departure of one of our co-founders, a \$0.8 million increase in insurance expense, a \$0.1 million increase in professional fees related to accounting, audit and legal services, and a \$0.1 million increase in depreciation expense.

Interest Income

Interest income was \$0.1 million and \$1,000 for the three months ended June 30, 2021 and 2020, respectively. The increase of \$0.1 million was due to higher average cash and cash equivalent balances after our December 2020 IPO.

Interest Expense

Interest expense was \$1,000 and \$0.8 million for the three months ended June 30, 2021 and 2020, respectively. The decrease of \$0.8 million was due to reduced interest expense as a result of the settlement of all of our convertible debt in July 2020.

Change in Fair Value of Derivative Liability

Change in fair value of derivative liability was \$0 and \$0.8 million for the three months ended June 30, 2021 and 2020, respectively. The decrease of \$0.8 million was primarily due to changes in the fair value of embedded derivatives issued in connection with our outstanding convertible promissory notes which all settled in July 2020.

Extinguishment of Convertible Debt

Extinguishment of convertible debt was \$0 and \$0.2 million for the three months ended June 30, 2021 and 2020, respectively. The \$0.2 million in recognized losses on extinguishment during the three months ended June 30, 2020 were related to the amendment of the terms of certain outstanding convertible promissory notes that we concluded were extinguishments.

Comparison of the Six Months Ended June 30, 2021 and 2020

	Six Months Ended June 30,		Change
	2021	2020	
(in thousands)			
Collaboration revenue	\$ 250	\$ 279	\$ (29)
Operating expenses:			
Research and development	25,273	4,584	20,689
General and administrative	24,234	1,324	22,910
Total operating expenses	49,507	5,908	43,599
Loss from operations	(49,257)	(5,629)	(43,628)
Other income (expense):			
Interest income	178	6	172
Interest expense	(3)	(1,301)	1,298
Change in fair value of derivative liability	—	(728)	728
Extinguishment of convertible debt	—	(174)	174
Total other income (expense)	175	(2,197)	2,372
Consolidated net loss and comprehensive loss	\$ (49,082)	(7,826)	(41,256)

Collaboration Revenue

Collaboration revenue for the six months ended June 30, 2021 was \$0.3 million, which consisted solely of revenue recognized under our legacy service contracts. There was no revenue recognized under our collaboration with BeiGene during the six months ended June 30, 2021. Collaboration revenue for six months ended June 30, 2020 was \$0.3 million, which consisted of revenue recognized under our collaboration agreement with BeiGene. Under the collaboration agreement with BeiGene, the remaining \$19.8 million of deferred revenue is expected to be earned upon transfer of the know-how and materials to BeiGene related to the manufacture of BA3071.

Research and Development Expense

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

	Six Months Ended June 30,		Change
	2021	2020	
(in thousands)			
External expenses:			
BA3011 (AXL-ADC)	\$ 9,777	\$ 1,558	\$ 8,219
BA3021 (ROR2-ADC)	5,378	1,471	3,907
Other CAB Programs	3,820	1,213	2,607
Total external expenses	18,975	4,242	14,733
Personnel and related	2,893	2,515	378
Equity-based compensation	2,109	(3,360)	5,469
Facilities and other	1,296	1,187	109
Total research and development expenses	\$ 25,273	\$ 4,584	\$ 20,689

Research and development expenses were \$25.3 million and \$4.6 million for the six months ended June 30, 2021 and 2020, respectively. The increase of \$20.7 million was primarily driven by a \$12.1 million increase in external costs due to manufacturing and ongoing clinical development for our clinical programs BA3011 and BA3021, a \$3.4 million increase in equity-based compensation related to a decrease in the fair value of awards under our profits interest plan during the six months ended June 30, 2020, a \$2.6 million increase in pre-clinical development for our other CAB programs, a \$2.1 million increase in stock-based compensation under our post-IPO equity incentive plans, a \$0.4 million increase in personnel related costs, and \$0.1 million increase in facility related costs.

General and Administrative Expense

General and administrative expenses were \$24.2 million and \$1.3 million for the six months ended June 30, 2021 and 2020, respectively. The increase of \$22.9 million was primarily driven by a \$14.8 million increase in stock-based compensation under our post-IPO equity incentive plans and the modification of awards issued to one of our co-founders, a \$4.2 million increase in equity-based compensation related to a decrease in the fair value of awards under our profits interest plan during the six months ended June 30, 2020, a \$1.5 million increase in insurance expense, a \$1.3 million increase in personnel related expenses as we expanded our administrative functions in support of our development activities and incurred severance benefits related to the departure of one of our co-founders, a \$0.8 million increase in professional fees related to accounting, audit and legal services, a \$0.3 million increase in other expenses including corporate franchise taxes and a \$0.2 million increase in depreciation expense.

Interest Income

Interest income was \$0.2 million and \$6,000 for the six months ended June 30, 2021 and 2020, respectively. The increase of \$0.2 million was due to higher average cash and cash equivalent balances after our December 2020 IPO.

Interest Expense

Interest expense was \$3,000 and \$1.3 million for the six months ended June 30, 2021 and 2020, respectively. The decrease of \$1.3 million was due to reduced interest expense as a result of the settlement of all of our convertible debt in July 2020.

Change in Fair Value of Derivative Liability

Change in fair value of derivative liability was \$0 and \$0.7 million for the six months ended June 30, 2021 and 2020, respectively. The decrease of \$0.7 million was primarily due to changes in the fair value during 2020 of embedded derivatives issued in connection with our outstanding convertible promissory notes which all settled in July 2020.

Extinguishment of Convertible Debt

Extinguishment of convertible debt was \$0 and \$0.2 million for the six months ended June 30, 2021 and 2020, respectively. The \$0.2 million in recognized losses on extinguishment during the six months ended June 30, 2020 were related to the amendment of the terms of certain outstanding convertible promissory notes that we concluded were extinguishments.

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 June 30, 2021, we had cash and cash equivalents of \$207.6 million.

Convertible and Promissory Notes

As of December 31, 2019, we had outstanding convertible notes with an aggregate principal balance of \$19.0 million and issued an additional \$2.8 million of convertible notes between March and April of 2020. All principal and accrued interest under the convertible notes was converted into our Series D convertible preferred stock in July 2020.

On April 22, 2020, we received proceeds from a loan, or PPP Loan, in the amount of \$0.7 million from City National Bank, as lender, pursuant to the Paycheck Protection Program, or PPP, of the CARES Act. The PPP Loan was evidenced by a promissory note, or Note, which contains customary events of default relating to, among other things, payment defaults and breaches of representations, warranties or terms of the PPP Loan documents. The PPP Loan was scheduled to mature on April 22, 2022 with monthly payments of principal and interest scheduled to begin in August 2021. Prepayment of the PPP Loan was permitted at any time prior to maturity with no prepayment penalties.

We applied for debt forgiveness on our PPP loan in June 2021. On July 2, 2021, we were notified by our lender, City National Bank, that our PPP Loan had been fully forgiven by the SBA and that there was no remaining balance on the PPP Loan. We expect to record 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 at least through the end of 2022. 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 the COVID-19 pandemic 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:

	Six Months Ended June 30,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (28,539)	\$ (6,866)
Investing activities	(736)	(86)
Financing activities	(1,721)	3,432
Net decrease in cash and cash equivalents	<u>\$ (30,996)</u>	<u>\$ (3,520)</u>

Cash Used in Operating Activities

Net cash used in operating activities totaled \$28.5 million for the six months ended June 30, 2021, which consisted of a consolidated net loss of \$49.1 million, a net change of \$3.1 million in our operating assets and liabilities and \$17.5 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 \$5.7 million, offset by an increase in prepaid expenses and other assets of \$2.6 million. The non-cash transactions primarily consisted of \$16.9 million of stock-based compensation and non-cash charges of \$0.6 million related to depreciation and amortization, offset by \$0.1 million of deferred rent.

Net cash used in operating activities for the six months ended June 30, 2020 was \$6.9 million, which consisted of a consolidated net loss of \$7.8 million and a net change of \$6.0 million in our net operating assets and liabilities, partially offset by a decrease of \$5.0 million in non-cash transactions. The net change in our operating assets and liabilities was primarily due to a decrease in prepaid expenses and other assets of \$0.4 million, and an increase in accounts payable and accrued expenses of \$5.9 million. The \$5.0 million change in non-cash transactions primarily consisted of a decrease in the profits interest liability of \$7.6 million primarily due to a decrease in the fair value of the underlying awards, partially offset by accrued interest of \$0.8 million on our outstanding convertible

debt, \$0.7 million related to the change in fair value of our derivative liability, \$0.5 million of non-cash interest, \$0.4 million related to depreciation and amortization and \$0.2 million related to the loss on the extinguishment of our convertible debt.

Cash Used in Investing Activities

Cash used in investing activities was \$0.7 million and \$0.1 million for the six months ended June 30, 2021 and 2020, respectively, related to the purchase of property and equipment.

Cash Provided by (Used In) Financing Activities

Net cash used in financing activities was \$1.7 million for the six months ended June 30, 2021, which consisted primarily of our payment of initial public offering costs of \$1.9 million, partially offset by the proceeds from the issuance of common stock under our Employee Stock Purchase Plan of \$0.2 million.

Net cash provided by financing activities was \$3.4 million for the six months ended June 30, 2020, which consisted primarily of proceeds from the issuance of \$2.8 million of convertible notes and a \$0.7 million PPP loan.

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, 2020. There have not been any material changes to the critical accounting policies discussed therein during the six months ended June 30, 2021.

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.

Not applicable to a smaller reporting company.

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 June 30, 2021. 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 June 30, 2021, 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 June 30, 2021 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 Annual Report on Form 10-K, including our consolidated financial statements and related notes appearing elsewhere in this prospectus 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 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 clinical trials, and therefore our receipt of necessary regulatory approvals could be delayed or prevented.
- 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 BA3011 and BA3021, 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 \$35.9 million and \$29.8 million for the years ended December 31, 2020 and 2019, respectively. For the three and six months ended June 30, 2021, our net losses were \$30.4 million and \$49.1 million, respectively. As of June 30, 2021, we had an accumulated deficit of \$140.0 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.

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, BA3011 and BA3021 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 June 30, 2021, we had approximately \$207.6 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 at least through the end of 2022. 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 BA3011 and BA3021;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts for BA3071;
- the progress of our current and future collaborators with whom we have entered or may in the future enter into collaborations and research and development agreements;
- the timing and amount of target specific indication and 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. 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, 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 BA3011 and BA3021, and we expect Phase 1 trials of BA3071 to initiate in 2021 with various other product candidates 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 registration-enabling Phase 2 trials for BA3011 in treatment-refractory sarcoma patients and PD-1 refractory NSCLC patients. The FDA has reviewed the trial designs, but has not opined on whether the Phase 2 clinical trials will in fact be sufficient to support regulatory approval. However, the FDA is expected to consider this further at the interim data review point. We cannot assure you that the FDA will agree that such data will be sufficient to support approval. 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:

- 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 would 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 BA3011 and BA3021, 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 BA3011 for the treatment of soft tissue and bone sarcoma and PD-1 refractory NSCLC, our Phase 2 clinical trial of BA3021 for the treatment of PD-1 refractory melanoma and NSCLC and 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 registration-enabling Phase 2 trials for BA3011 in treatment-refractory sarcoma patients and PD-1 refractory NSCLC. The FDA has reviewed the trial designs, but has not opined on whether the Phase 2 clinical trials will in fact be sufficient to support regulatory approval. However, the FDA is expected to consider this further at the interim data review point. We cannot assure you that the FDA will agree that such data will be sufficient to support approval. 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.

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.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials, such as the interim data from our ongoing Phase 2 clinical trials of BA3011 and BA3021. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. 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 topline 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 also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. 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 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 acceptable product candidate for use in clinical trials in a timely manner, or at all; or
- the COVID-19 pandemic, which 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 BA3011 and BA3021 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, our ability to obtain and maintain patient consents 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 BA3011 and BA3021, 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 BA3011 and BA3021 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, BA3011 and BA3021 are being studied in combination with other therapies, which may exacerbate adverse events associated with the therapy. Patients treated with BA3011, BA3021 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 BA3011 and BA3021 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, any of the following negative consequences could occur, including:

- 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 Risk Evaluation and Mitigation Strategy, or 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 BA3011 and BA3021 in combination with an anti-PD-1 inhibitor and plan to evaluate the use of BA3071 in combination with an anti-PD1 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 BA3011 and BA3021, 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 BA3011 and BA3021, we have developed a Clinical Laboratory Improvement Amendments, or CLIA, validated quantitative biomarker assay, the TmPS, which measures AXL and ROR2 expression levels on the tumor membrane and cytoplasm. 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 registrational studies and partner with the appropriate diagnostic provider to codevelop a companion diagnostic.

If safe and effective use of any of our product candidates, such as BA3011 and BA3021, 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. The process of obtaining or creating such diagnostic 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 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 BA3011 and BA3021.

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 immunoncology, 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 BA3011 and BA3021. 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 sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or 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. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation, including litigation challenging the constitutionality of the ACA.

For example, on December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act, or the TCJA. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and oral arguments were held on November 10, 2020, although it is unclear when a decision will be made or how the Supreme Court will rule. Although the Supreme Court has yet to rule on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business. We continue to evaluate the effect that the ACA

and its possible reform, repeal and replacement has on our business and exclusivity under the BPCIA. It is uncertain the extent to which any such changes may impact our business or financial condition.

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 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 an accelerated approval for BA3011 and BA3021 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. However, full approval of another product for the same indication as any of our product candidates for which we are seeking accelerated approval may make accelerated approval of our product candidates more difficult. If granted, accelerated approval is contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit and, in some cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to submission of the application or approval. 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.

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. In the United States, for example, 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, at the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The HHS has solicited feedback on some of these measures and has implemented others under its existing authority. 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 BA3011 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 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, including 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. Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have passed. On December 22, 2017, President Trump signed into law federal tax legislation commonly referred to as the TCJA, which includes a provision repealing, 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". In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018 among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In December 2018, CMS published a new final rule permitting further collections and payments to and from

certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the TCJA. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, and oral arguments were held on November 10, 2020, although it is unclear when a decision will be made or how the Supreme Court will rule. Although the Supreme Court has yet to rule on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, 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, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional congressional action is taken. In addition, the CARES Act suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020. 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. For example, at the federal level, the Trump administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration’s budget proposal for the fiscal year 2020 contained further drug price control measures that could be enacted during the budget process or in future legislation, including, for example, measures to permit

Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Although a number of these and other measures may require additional authorization to become effective, Congress or the executive branch have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

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 are 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, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, the U.S. federal physician transparency reporting requirements will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners; 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 process and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. Moreover, the United Kingdom leaving the European Union could also lead to further legislative and regulatory changes. Further, from January 1, 2021, we will have to 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. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, 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. In addition, 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. The CCPA 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 laws and regulations 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 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. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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:

- identifying, recruiting, integrating, maintaining and motivating additional employees;

- managing our internal development efforts effectively, including the clinical and regulatory review process for BA3011 and BA3021 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 BA3011, BA3021 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 perform 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 contractors or consultants to implement these tasks going forward. Because we rely on numerous consultants, effectively outsourcing many key functions of our business, 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 BA3011, BA3021 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 BA3011, BA3021 and any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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 of or destruction of our proprietary and confidential data, employee data or personal data, which could result in additional costs, significant liabilities, harm to our reputation and material disruption of our operations.

Despite the implementation of security measures, our internal computer systems 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 damage from various methods, including cybersecurity attacks, breaches, intentional or accidental mistakes or errors, or other technological failures, which can include, among other things, computer viruses, 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, sophistication and intensity, and are becoming increasingly difficult to detect. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy 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. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable 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. 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 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 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, which is U.S. owned, but governed by Chinese laws, rules and regulations and have a collaboration with BeiGene, a company headquartered in 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 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. For example, a trade war could lead to increased costs for clinical materials that are manufactured in China. These interruptions or failures could also impede 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. 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 China, the European Union, Australia, New Zealand, and Japan. We conduct preclinical research and development activities in China through BioDuro, which is U.S. owned, but governed by Chinese laws, and have a collaboration with BeiGene, a company headquartered in 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:

- 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.

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 clinical trials, and therefore our receipt of necessary regulatory approvals could be delayed or prevented.

We face risks related to health epidemics or outbreaks of communicable diseases. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, emerged in China. Since then, COVID-19 has spread to multiple countries worldwide, including the United States and member states of the European Union. 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. For example, our primary operations are located in San Diego, California, and San Diego County and the State of California had issued shelter-in-place orders in response to the COVID-19 pandemic. Although 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, in response to local surges and new waves of infection, including those caused by the spread of the Delta variant, some countries, states, and local governments have maintained or reinstated these restrictions, or may reinstate 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. In March 2020, we implemented a remote working policy for many of our employees, began restricting non-essential travel. 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. 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 variant), 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 not experienced material business disruptions, including with respect to any of the clinical trials we are conducting, or impairments of any of our assets as a result of the pandemic, the continued spread of COVID-19 globally 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. For example, we have entered into a Global Co-Development and Collaboration Agreement with BeiGene for the development, manufacturing and commercialization of BA3071. Under the terms of our BeiGene collaboration, BeiGene is generally responsible for developing BA3071 and is responsible for global regulatory filings and commercialization. Subject to the terms of the agreement, BeiGene holds an exclusive license with us to develop and manufacture the product candidate globally. BeiGene is responsible for all costs of development, manufacturing and commercialization globally. We are currently in preliminary discussions with BeiGene regarding the allocation of roles and responsibilities under our Global Co-Development and Collaboration Agreement with BeiGene, including with respect to the initiation of the Phase I trial for 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. 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 BA3011 and BA3021. Because we rely on these third parties and do not have the ability to

conduct preclinical studies or clinical trials independently, we will 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 will not be 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 may 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 cannot 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. In all events, we will be 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 Good Laboratory Practices, or 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 will 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:

- 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 and 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. As of December 31, 2020, we own or have rights to 266 issued or allowed patents and 226 pending patent applications worldwide. 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 August 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 2041 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 and 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:

- 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 collaborator, our future collaborators or our competitors, and the timing of these introductions or announcements;
- 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 June 30, 2021, executive officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own approximately 42.9% 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, owns 7.3%, of our outstanding common stock, as of June 30, 2021.

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 managers of Inversagen, LLC and BioAtla Holdings, LLC and directors 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.

We are an “emerging growth company” and a “smaller reporting company,” and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded \$700.0 million as of the prior June 30th and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. We will cease to be an emerging growth company as of December 31, 2021.

An emerging growth company may take advantage of specified reduced reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited financial statements and only two years of related Management’s discussion and analysis of financial condition and results of operations;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotations;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirement to hold a nonbinding advisory vote on executive compensation and to obtain stockholder approval of any golden parachute payments not previously approved.

We have elected to take advantage of certain of the reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our investors may be different from the information you might receive from other public reporting companies that are not emerging growth companies in which you hold equity interests. The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to take advantage of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either irrevocably elect to “opt out” of such extended transition period or no longer qualify as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a “smaller reporting company,” meaning that the market value of our shares held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company with less than \$100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We will cease to be a smaller reporting company as of December 31, 2021.

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.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new 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 are no longer an emerging growth company or a smaller reporting company, we will 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required 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 will be required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our second annual report on Form 10-K after we become a public company, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company or a smaller reporting company with less than \$100 million in annual revenue, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of 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.

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 will 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 June 30, 2021, we have not used any of the proceeds from our IPO and 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
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 June 30, 2021, 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.

