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, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-40703

Adagio Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-1403134**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1601 Trapelo Road, Suite 178 Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 819-0080

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the 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 8, 2022, the registrant had 108,830,525 shares of common stock, $0.0001 par value per share, outstanding.

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SUMMARY OF RISK FACTORS

The following summarizes the principal factors that make an investment in us speculative or risky, all of which are more fully described in the Risk Factors section below. This summary should be read in conjunction with the Risk Factors section and should not be relied upon as an exhaustive summary of the material risks facing our business.

Risks Related to our Financial Position and Capital Needs

- We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.
- We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.
- We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Risks Related to the Development of our Product Candidates

- Based on feedback received from the FDA in the second quarter of 2022, we decided to pause our planned submission of an Emergency Use Authorization ("EUA") request for adintrevimab as a result of the Omicron BA.2 sublineage becoming the predominant variant in the United States. Published data has shown that in *in vitro* assays, adintrevimab has markedly reduced neutralization activity against the Omicron BA.2, BA.4, and BA.5 sublineages. While we intend to continue to engage with the FDA and to monitor the evolution of SARS-CoV-2 and the *in vitro* activity of adintrevimab against predominant variants in the United States to determine the optimal timing for an EUA request, we cannot be certain that adintrevimab will neutralize future variants and that we will submit an EUA for adintrevimab or whether an EUA will be granted if we do submit such request.
- All of our product candidates are currently in clinical and preclinical development. If we are unable to successfully develop, receive regulatory approval or EUA for and commercialize our product candidates for the indications we seek, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.
- Because adintrevimab and any future product candidates represent novel approaches to the prevention and treatment of disease, there are many uncertainties regarding the development, market acceptance, third-party reimbursement coverage and commercial potential of our product candidates.
- Newly emerging and future SARS-CoV-2 variants could reduce the activity and effectiveness of adintrevimab as a potential prevention of or treatment for symptomatic COVID-19. We may not be able to modify adintrevimab to improve binding to such variants and obtain sufficient data on the activity and effectiveness of re-engineered adintrevimab in order to support an EUA or regulatory approval, and we may not be successful in identifying new antibodies that are suitable either as monotherapy or as combination therapy to mitigate the risk of reduced activity against future SARS-CoV-2 variants.
- There can be no assurance that the Public Health Emergency (as defined herein) will continue to be in place for an extended period of time and that the product we are developing for COVID-19 could be granted an EUA by the FDA or similar authorization by regulatory authorities outside of the United States if we decide to apply for such an authorization. If we do not apply for such an authorization or, if we do apply and no authorization is granted or, once granted, it is terminated, we will be unable to sell our product in the near future and instead, will be required to pursue solely the traditional regulatory approval processes of the FDA and comparable foreign authorities, which are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.
- Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval.
- Lack of awareness or negative public opinion of monoclonal antibody therapies and increased regulatory scrutiny of monoclonal antibody therapies to prevent or treat COVID-19 may adversely impact the development or commercial success of our current and future product candidates.
- We may experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, or we may pause, delay or terminate enrollment in our clinical trials, which could in turn delay or prevent our receipt of necessary regulatory approvals.

- We may not be successful in our efforts to build a pipeline of additional product candidates through internal efforts or through partnerships for discovery of novel antibody product candidates.
- Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.

Risks Related to the Manufacturing of our Product Candidates

- Monoclonal antibody therapies are complex and difficult to manufacture. We could experience manufacturing problems or may be unable to access raw materials due to global supply chain shortages, that result in delays in the development or commercialization of our product candidates or otherwise harm our business.

Risks Related to the Commercialization of Our Product Candidates

- The affected populations for adintrevimab or our other product candidates may be smaller than we or third parties currently project, which may affect our ability to enroll our clinical trials as well as the addressable markets for our product candidates.
- Adintrevimab and our other monoclonal antibody product candidates may face significant competition from vaccines, antiviral agents and other therapeutics for COVID-19 that are currently available or in development.

Risks Related to Our Intellectual Property

- If we are unable to obtain, maintain and enforce patent protection for our current and future product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.
- Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

- We previously identified a material weakness in our internal control over financial reporting. We may identify future material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we fail to establish and maintain adequate internal control over financial reporting, we may not be able to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective, which may adversely affect our business.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ADAGIO THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share and per share amounts)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 474,885	$ 542,224
Marketable securities	—	49,194
Prepaid expenses and other current assets	6,476	25,293
Total current assets	481,361	616,711
Property and equipment, net	91	83
Operating lease right-of-use assets	2,861	—
Other non-current assets	299	3,297
Total assets	$ 484,612	$ 620,091
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 14,232	$ 5,783
Accrued expenses	52,624	56,277
Operating lease liabilities, current	969	—
Other current liabilities	58	—
Total current liabilities	67,883	62,060
Early-exercise liability	1	6
Operating lease liabilities, non-current	1,889	—
Other non-current liability	—	6
Total liabilities	69,773	62,072
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 109,773,173 shares issued and 108,780,525 shares outstanding at June 30, 2022; 1,000,000,000 shares authorized, 111,251,660 shares issued and 110,782,909 shares outstanding at December 31, 2021	11	11
Treasury stock, at cost; 992,648 shares and 468,751 shares at June 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	858,593	850,125
Accumulated other comprehensive loss	—	(8)
Accumulated deficit	(443,765)	(292,109)
Total stockholders' equity (deficit)	414,839	558,019
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 484,612	$ 620,091

The accompanying notes are an integral part of these condensed consolidated financial statements.

ADAGIO THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

(In thousands, except share and per share amounts)

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Operating expenses:				
Research and development[1]	$ 37,129	$ 35,067	$ 129,164	$ 69,204
Acquired in-process research and development[2]	—	2,500	—	3,500
Selling, general and administrative	14,620	7,124	23,324	10,695
Total operating expenses	51,749	44,691	152,488	83,399
Loss from operations	(51,749)	(44,691)	(152,488)	(83,399)
Other income (expense):				
Other income (expense), net	759	18	832	26
Total other income (expense), net	759	18	832	26
Net loss	(50,990)	(44,673)	(151,656)	(83,373)
Other comprehensive income (loss)				
Unrealized gain on available-for-sale securities, net of tax	—	—	8	—
Comprehensive loss	$ (50,990)	$ (44,673)	$ (151,648)	$ (83,373)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.47)	$ (178.86)	$ (1.40)	$ (663.94)
Weighted-average common shares outstanding, basic and diluted	108,166,890	249,769	108,019,051	125,574

(1) Includes related-party amounts of $2,285 and $4,285 for the three and six months ended June 30, 2022, respectively, and $247 and $435 for the three and six months ended June 30, 2021, respectively (see Note 15).

(2) Includes no related-party amounts for both the three and six months ended June 30, 2022, and $2,500 and $3,500 for the three and six months ended June 30, 2021, respectively (see Note 15).

The accompanying notes are an integral part of these condensed consolidated financial statements.

ADAGIO THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(UNAUDITED)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	(Deficit)
Balances at December 31, 2020	12,647,934	$ 169,548	5,593,240	$ 1	22,600,000	$ (85)	$ 154	$ —	$ (65,319)	$ (65,249)
Stock-based compensation expense	—	—	—	—	—	—	587	—	—	587
Net loss	—	—	—	—	—	—	—	—	(38,700)	(38,700)
Balances at March 31, 2021	12,647,934	$ 169,548	5,593,240	$ 1	22,600,000	$ (85)	$ 741	$ —	$ (104,019)	$ (103,362)
Issuance of Series C convertible preferred stock, net of issuance costs of $337	4,296,550	335,163	—	—	—	—	—	—	—	—
Issuance of common stock	—	—	6,000	—	—	—	66	—	—	66
Stock-based compensation expense	—	—	—	—	—	—	3,342	—	—	3,342
Vesting of restricted common stock from early-exercised options	—	—	—	—	—	—	3	—	—	3
Retirement of treasury stock	—	—	—	—	(22,600,000)	85	(85)	—	—	—
Net loss	—	—	—	—	—	—	—	—	(44,673)	(44,673)
Balances at June 30, 2021	16,944,484	$ 504,711	5,599,240	$ 1	$ —	$ —	$ 4,067	$ —	$ (148,692)	$ (144,624)

	Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	(Deficit)
Balances at December 31, 2021	—	$ —	110,782,909	$ 11	468,751	$ —	$ 850,125	$ (8)	$ (292,109)	$ 558,019
Vesting of restricted common stock from early-exercised options	—	—	—	—	—	—	1	—	—	1
Exercise of stock options	—	—	50,353	—	—	—	47	—	—	47
Repurchase of unvested restricted common stock	—	—	(1,158,089)	—	1,158,089	—	—	—	—	—
Retirement of treasury stock	—	—	—	—	(1,626,840)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,983	—	—	1,983
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	—	—	8	—	8
Net loss	—	—	—	—	—	—	—	—	(100,666)	(100,666)
Balances at March 31, 2022	—	$ —	109,675,173	$ 11	—	$ —	$ 852,156	$ —	$ (392,775)	$ 459,392
Exercise of stock options	—	—	98,000	—	—	—	76	—	—	76
Repurchase of unvested restricted common stock	—	—	(992,648)	—	992,648	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	6,361	—	—	6,361
Net loss	—	—	—	—	—	—	—	—	(50,990)	(50,990)
Balances at June 30, 2022	—	$ —	108,780,525	$ 11	992,648	$ —	$ 858,593	$ —	$ (443,765)	$ 414,839

The accompanying notes are an integral part of these condensed consolidated financial statements.

ADAGIO THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)

	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Cash flows from operating activities:		
Net loss	$ (151,656)	$ (83,373)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,344	3,929
Non-cash payments	—	66
Net amortization of premiums and accretion of discounts on marketable securities	194	—
Amortization of operating lease right-of-use assets	211	—
Depreciation expense	9	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	18,825	(1,146)
Other non-current assets	2,998	—
Accounts payable	8,449	2,159
Accrued expenses	(3,653)	21,054
Other current liabilities	58	—
Operating lease liabilities	(214)	—
Other non-current liabilities	(6)	—
Net cash used in operating activities	(116,441)	(57,311)
Cash flows from investing activities:		
Maturities of marketable securities	49,000	—
Purchases of property and equipment	(17)	—
Net cash provided by investing activities	48,983	—
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs paid	—	335,264
Payments of initial public offering costs	—	(432)
Proceeds from exercises of stock options	123	—
Payments for repurchases of unvested restricted common stock	(4)	—
Net cash provided by financing activities	119	334,832
Net (decrease) increase in cash and cash equivalents	(67,339)	277,521
Cash and cash equivalents at beginning of period	542,224	114,988
Cash and cash equivalents at end of period	$ 474,885	$ 392,509
Supplemental disclosure of non-cash investing and financing activities:		
Operating lease right-of-use asset recognized upon adoption of ASC 842	$ 1,728	$ —
Operating lease right-of-use asset recognized under ASC 842	$ 1,344	
Deferred offering and issuance costs included in accrued expenses	$ —	$ 1,602

The accompanying notes are an integral part of these condensed consolidated financial statements.

1. Nature of the Business and Basis of Presentation

Adagio Therapeutics, Inc., together with its consolidated subsidiaries (the "Company"), is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of differentiated products for the prevention and treatment of infectious diseases. The Company is developing its lead product candidate, adintrevimab, for the prevention and treatment of COVID-19, the disease caused by the virus SARS-CoV-2 and its variants. Adintrevimab is designed to be a potent, long-acting and broadly neutralizing antibody for both the prevention and treatment of COVID-19. The Company initiated clinical trials for adintrevimab in February 2021 and due to the emergence and global spread of the Omicron variant, against which adintrevimab has reduced in vitro neutralization potency compared to prior variants, enrollment in both EVADE (evaluating adintrevimab for the prevention of COVID-19) and STAMP (evaluating adintrevimab for the treatment of COVID-19) was paused in January 2022. The Company reported preliminary safety and efficacy data (pre-Omicron) from both its EVADE and STAMP trials in March 2022

The BA.4 and BA.5 sublineages of the SARS-CoV-2 Omicron variant, which have shown reduced in vitro susceptibility to monoclonal antibodies, have recently emerged as the current predominant variants of SARS-CoV-2 in the United States. Adintrevimab, which has demonstrated broadly neutralizing activity *in vitro* against SARS-CoV-2 variants of concern ("VOCs") including Alpha, Beta, Delta, Delta Plus, Gamma and Omicron BA.1, has markedly reduced neutralization activity *in vitro* against the Omicron BA.2, BA.4, and BA.5 sublineages. Based on feedback from the FDA regarding adintrevimab's lack of neutralizing activity against the BA.2 variant, the Company paused the submission of an Emergency Use Authorization ("EUA") request.

The Company is advancing proprietary antibodies targeting distinct sites with activity against all SARS-CoV-2 VOCs to date, including the Omicron variant and its sublineages, and plans to take a combination of these antibodies into clinical trials in the first quarter of 2023 for the prevention and treatment of COVID-19. Beyond COVID-19, the Company is leveraging robust antibody discovery and development capabilities that have enabled expedited advancement of adintrevimab into clinical trials to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and influenza. The Company was incorporated in the State of Delaware in June 2020. The Company operates as a virtual company and maintains a corporate headquarters for general and administrative purposes only. The Company performs research and development activities internally and engages third parties, including Adimab, LLC ("Adimab"), to perform ongoing research and development and other services on its behalf.

The Company is subject to a number of risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, completing clinical trials, the ability to raise additional capital to fund operations, obtaining regulatory approval for product candidates, market acceptance of products, competition from substitute products, protection of proprietary intellectual property, compliance with government regulations, the impact of COVID-19, dependence on key personnel, the ability to attract and retain qualified employees, and reliance on third-party organizations for the discovery, manufacturing, clinical and commercial success of its product candidates.

In July 2021, the Company effected a five-for-one stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 9). Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the preferred stock conversion ratios.

In August 2021, the Company completed its initial public offering ("IPO") pursuant to which it issued and sold 20,930,000 shares of its common stock, including 2,730,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were approximately $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all shares of the Company's convertible preferred stock then outstanding converted into 84,722,420 shares of common stock (see Note 10).

The Company has not generated any revenue since inception. The Company's lead product candidate could require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales, including government supply contracts.

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has primarily funded its operations with proceeds from sales of convertible preferred stock and proceeds from the Company's IPO. The Company has incurred losses and negative cash flows from operations since its inception, including a net loss of $151.7 million for the six months ended June 30, 2022. As of June 30, 2022, the Company had an accumulated deficit of $443.8 million. The Company expects to continue to generate operating losses for the foreseeable future. The Company expects that its existing cash and cash equivalents will be sufficient

to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of the interim condensed consolidated financial statements.

The Company expects to seek additional funding through equity offerings, government or private-party grants, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or rights of the Company's stockholders.

If the Company is unable to obtain sufficient capital, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Impact of the COVID-19 Coronavirus

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. The evolving and constantly changing impact of the pandemic will directly affect the potential commercial prospects of adintrevimab and other product candidates for the prevention and treatment of COVID-19. The severity of the COVID-19 pandemic and the continued emergence of variants of concern (such as the widespread Omicron variant and its sublineages and the Delta variant), the availability, administration and acceptance of vaccines, monoclonal antibodies, antiviral agents and other therapeutic modalities, vaccine mandates by employers and/or local or national governments, and the potential development of "herd immunity" by the global population will affect the design and enrollment of the Company's clinical trials, the potential regulatory authorization or approval of the Company's product candidates and the commercialization of the Company's product candidates, if approved.

In addition, the Company's business and operations may be more broadly adversely affected by the COVID-19 pandemic. The COVID-19 outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen. The global COVID-19 pandemic continues to evolve rapidly, and the Company will continue to monitor it closely. The ultimate extent of the impact of the COVID-19 pandemic on the Company's business, financial condition, operations and product development timelines and plans remains highly uncertain and will depend on future developments, including the duration and spread of outbreaks and the continued emergence of variants, its impact on the Company's clinical trial design and enrollment, trial sites, contract research organizations ("CROs"), contract development and manufacturing organizations ("CDMOs"), and other third parties with which the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. To date, the Company has experienced some delays and disruptions in its development activities as a result of the COVID-19 pandemic. Some of the Company's CROs, CDMOs and other service providers also continue to be impacted. The Company will continue to monitor developments as it addresses the disruptions, delays and uncertainties relating to the COVID-19 pandemic. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results and operations may be materially adversely affected and may affect the Company's ability to raise capital.

Basis of Presentation

The Company's condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying condensed consolidated financial statements include the accounts of Adagio Therapeutics, Inc. and its wholly owned subsidiaries, Adagio Therapeutics Security Corporation, Adagio Therapeutics Switzerland GmbH, and Adagio Therapeutics Netherlands B.V. All intercompany accounts and transactions have been eliminated in consolidation. The Company views its operations and manages its business in one operating segment, which is the business of discovering, developing and commercializing differentiated products for the prevention and treatment of infectious diseases.

2. Summary of Significant Accounting Policies

As of June 30, 2022, the Company's significant accounting policies and estimates, which are detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the U.S. Securities and Exchange Commission ("SEC") on March 31, 2022 (as subsequently amended by Amendment No. 1 to the Company's Annual Report on Form 10-K, filed with the SEC on April 29, 2022, the "2021 Form 10-K") have not changed except as discussed below.

Leases

Effective January 1, 2022, the Company adopted ASU No. 2016-02, *Leases (Topic 842)* ("ASC 842") using the required modified retrospective approach and utilizing the effective date as its date of initial application. As a result, prior periods are presented in accordance with the previous guidance in ASC 840, *Leases* ("ASC 840").

The Company evaluates whether an arrangement is or contains a lease at the inception date. If determined to be or contain a lease, the Company determines the classification of the lease at the commencement date, which represents the date at which the lessor makes the underlying asset available for use by the Company. When determining the expected accounting lease term, the Company includes the noncancellable lease term, together with periods covered by (i) an option to extend the lease if the Company is reasonably certain to exercise such option, (ii) an option to terminate the lease if the Company is reasonably certain not to exercise such option and (iii) an option to extend or not terminate the lease where the exercise of such option is controlled by the lessor. The Company has elected the short-term lease exemption, which allows the Company to not recognize lease liabilities and right-of-use assets arising from lease arrangements with original lease terms of twelve months or less. The Company elected the practical expedient to not separate lease and non-lease components for its leases.

Right-of-use assets represent the Company's right to use an underlying asset over the lease term and lease liabilities represent the Company's obligation to make lease payments under the arrangement. The Company measures its lease liabilities as the present value of the lease payments, discounted using an incremental borrowing rate, as interest rates implicit in lease arrangements are generally not readily determinable. The Company measures its right-of-use assets as the present value of its lease payments at the commencement date. The incremental borrowing rate represents the interest rate at which the Company could borrow an amount equal to the lease payments on a fully collateralized basis, over a similar term, in a similar economic environment. The Company recognizes rent expense for operating leases on a straight-line basis. The Company recognizes variable lease expenses as incurred.

The Company remeasures right-of-use assets and lease liabilities when a lease is modified, and the modification is not accounted for as a separate contract. A modification is accounted for as a separate contract if the modification grants the Company an additional right of use not included in the original lease arrangement and the increase in lease payments is commensurate with the additional right of use. The Company assesses its right-of-use assets for impairment in a manner consistent with its assessment for long-lived assets held and used in operations.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of June 30, 2022, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2022 and 2021, the condensed consolidated statements of cash flows for the six months ended June 30, 2022 and 2021 and the condensed consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the three and six months ended June 30, 2022 and 2021 are unaudited.

The accompanying unaudited condensed consolidated financial statements as of June 30, 2022 and for the three and six months ended June 30, 2022 and 2021 have been prepared by the Company pursuant to the rules and regulations of the SEC for interim financial statements. The accompanying consolidated balance sheet as of December 31, 2021 was derived from audited financial statements, but does not include all disclosures required by GAAP. Certain information and footnote disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited annual consolidated financial statements, and the notes thereto, as of and for the year ended December 31, 2021, which are included in the Company's 2021 Form 10-K.

In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's condensed consolidated financial position as of June 30, 2022 and December 31, 2021, the condensed consolidated results of operations for the three and six months ended June 30, 2022 and June 30, 2021, the condensed consolidated cash flows for the six months ended June 30, 2022 and June 30, 2021 and changes in stockholders' equity (deficit) for the three and six months ended June 30, 2022 and June 30, 2021 have been made. The Company's condensed consolidated results of operations for the three and six months ended June 30, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, research and development expenses and related prepaid or accrued costs. Prior to the IPO, significant estimates and assumptions also included the valuation of common stock and resulting stock-based compensation expense. The Company bases its estimates on historical experience, known trends and other market-specific or relevant factors it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience.

Changes in estimates are recorded in the period in which they become known. Actual results may differ materially from those estimates or assumptions.

The Company is monitoring the potential impact of the COVID-19 pandemic on its business and condensed consolidated financial statements. The Company is not aware of any specific event or circumstance that would require any update to its estimates or judgments reflected in these condensed consolidated financial statements or a revision of the carrying value of its assets or liabilities as of the issuance date of these condensed consolidated financial statements. These estimates may change as new events occur and additional information is obtained.

Recently Issued and Adopted Accounting Pronouncements

The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for nonpublic companies.

In February 2016, the FASB issued ASC 842, as subsequently amended. ASC 842 sets forth the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). ASC 842 replaces the existing guidance in ASC 840. ASC 842 requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. A lessee is also required to record (i) a right-of-use asset and a lease liability on its balance sheets for all leases with a term of greater than 12 months regardless of their classification and (ii) lease expense on its statement of operations for operating leases and amortization and interest expense on its statement of operations for financing leases. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases under ASC 840. The Company adopted the new standard and used the modified retrospective approach with January 1, 2022 as the initial date of application. The Company elected the available package of practical expedients which allowed the Company to not reassess previous accounting conclusions around whether arrangements are or contain leases, the classification of leases, and the treatment of initial direct costs. As a result of the adoption of ASC 842, the Company recorded (i) an operating lease liability, current of $0.3 million, (ii) an operating lease liability, non-current of $1.4 million and (iii) an operating lease right-of-use asset of $1.7 million, net of the unamortized balance of deferred rent liability as of the transition date. There was no impact from the adoption of ASC 842 to the Company's results of operations and cash flows from operations. A summary of the impact of the adoption is as follows (in thousands):

	December 31, 2021	Impact of Adoption	January 1, 2022
Operating lease right-of-use asset	$ —	$ 1,728	$ 1,728
Operating lease liability, current	—	308	308
Other non-current liability	6	(6)	—
Operating lease liability, non-current	—	1,426	1,426

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04 and ASU 2019-05 (collectively, "Topic 326"). The main objective of this update and amendments is to provide information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date and utilize a methodology that requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities are required to be recorded through an allowance for credit losses. The update limits the recognition of the amount of credit losses for available-for-sale debt securities to the amount by which the carrying value exceeds fair value. The measurement will be based on relevant information, including historical experience, current conditions and reasonable and supportable forecasts that affect the collectability of the reported amount and requires disclosure requirements related to credit risks. For public entities that qualify as a filer with the Securities and Exchange Commission, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years and early adoption is permitted. In November 2019, the FASB deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. ASU 2016-13 is applied by means of a cumulative-effect adjustment to the opening retained earnings as of the beginning of the first reporting period in which the guidance is effective. The Company is currently evaluating the potential impact that the adoption of this standard may have on its consolidated financial statements and related disclosures.

3. Marketable Securities

Treasury securities held by the Company are classified as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities, and carried at fair value in the accompanying condensed consolidated balance sheet on a settlement date basis.

The Company did not hold any available-for-sale marketable securities as of June 30, 2022.

The following tables summarize the gross unrealized gains and losses of the Company's marketable securities as of December 31, 2021 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury securities	$ 49,202	$ —	$ (8)	$ 49,194

No available-for-sale marketable securities held as of December 31, 2021 had remaining maturities greater than twelve months.

4. Fair Value Measurements

Fair Value Measurements

Certain assets of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above. The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at June 30, 2022:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 473,995	$ —	$ —	$ 473,995
	$ 473,995	$ —	$ —	$ 473,995

	Fair Value Measurements at December 31, 2021:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 541,220	$ —	$ —	$ 541,220
Marketable securities:				
U.S. Treasury securities	49,194	—	—	49,194
	$ 590,414	$ —	$ —	$ 590,414

The money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy.

The Company did not hold any U.S. Treasury securities as of June 30, 2022.

There were no changes to the valuation methods during the three and six months ended June 30, 2022 or 2021.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers into or out of Level 1, Level 2 or Level 3 fair value measurements during the three and six months ended June 30, 2022 or 2021.

5. Prepaid Expenses and Other Current Assets

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

	June 30, 2022	December 31, 2021
Prepaid external research, development and manufacturing costs	$ 4,392	$ 20,582
Prepaid insurance	456	3,190
Prepaid compensation and other	1,628	1,521
	$ 6,476	$ 25,293

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Accrued external research, development and manufacturing costs	$ 44,919	$ 48,590
Accrued professional and consultant fees	4,142	2,155
Accrued employee compensation	3,443	4,945
Other	120	587
	$ 52,624	$ 56,277

7. License and Collaboration Agreements

Adimab Assignment Agreement

In July 2020, the Company entered into an Assignment and License Agreement with Adimab ("Adimab Assignment Agreement"). Under the terms of the agreement, Adimab assigned to the Company all rights, title and interest in and to certain of its coronavirus-specific antibodies (each, a "CoV Antibody" and together, the "CoV Antibodies"), including modified or derivative forms thereof, and related intellectual property ("Adimab CoV Assets"). In addition, Adimab granted to the Company a non-exclusive, worldwide, royalty-bearing, sublicensable license to certain of its platform patents and technology for the development, manufacture and commercialization of the CoV Antibodies and pharmaceutical products containing or comprising one or more CoV Antibodies (each, a "Product") for all indications and uses, with the exception of certain diagnostic uses and use as a research reagent (the "Field"). The Company is entitled to sublicense the assigned rights and licensed intellectual property solely with respect to any CoV Antibody or Product, subject to specified conditions of the agreement. The Company is obligated to use commercially reasonable efforts to achieve specified

development and regulatory milestones for Products in certain major markets and to commercialize a product in any country in which the Company obtains marketing approval.

Pursuant to the terms of the Adimab Assignment Agreement, the parties will establish one or more work plans that set forth the activities to be performed under the agreement (each, a "Work Plan"), and each party is responsible for performing the obligations to which it is assigned under such Work Plans. Upon execution of the Adimab Assignment Agreement, the Company and Adimab agreed on an initial Work Plan that outlined the services that will be performed commencing at inception of the arrangement. The Company is obligated to pay Adimab quarterly for its services performed under each Work Plan at a specified full-time equivalent rate. Otherwise, the Company is solely responsible for the development, manufacture and commercialization of the CoV Antibodies and associated Products at its own cost and expense. The Company is solely responsible for preparing and submitting all investigational new drug applications, new drug applications, biologics license applications and other regulatory filings for the CoV Antibodies and Products in the Field, and for obtaining and maintaining all marketing approvals for Products in the Field, at its sole expense. Additionally, the Company has the sole right to prosecute, maintain, enforce and defend patents covering the CoV Antibodies and Products, all at its own expense.

Amounts paid with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement are recognized as research and development expense as such amounts are incurred. For the three and six months ended June 30, 2022, the Company recognized $0.2 million and $0.5 million, respectively, of research and development expense in connection with services provided by Adimab. For the three and six months ended June 30, 2021, the Company recognized $0.2 million and $0.4 million, respectively, of expense in connection with services provided by Adimab. Please refer to Note 15 for additional information.

In July 2020, in consideration for the rights assigned and license conveyed under the Adimab Assignment Agreement, the Company issued 5,000,000 shares of its Series A convertible preferred stock (the "Series A Preferred Stock"), then having a fair value of $40.0 million, to Adimab. Concurrently, Adimab relinquished 21,250,000 shares of the Company's common stock to the Company, then having a fair value of $85,000. Additionally, the Company is obligated to pay Adimab up to $16.5 million upon the achievement of specified development and regulatory milestones for the first Product under the agreement that achieves such specified milestones and up to $8.1 million upon the achievement of specified development and regulatory milestones for the second Product under the agreement that achieves such specified milestones. The maximum aggregate amount of milestone payments payable under the agreement for any and all Products is $24.6 million; however, milestone payments do not accrue for certain *in vitro* diagnostic devices consisting of or containing CoV Antibodies.

In February 2021, the Company achieved the first specified milestone under the agreement upon dosing of the first patient in a Phase 1 global clinical trial evaluating adintrevimab, which obligated the Company to make a $1.0 million milestone payment to Adimab. In April 2021, the Company achieved the second specified milestone under the agreement upon dosing of the first patient in a Phase 2 global clinical trial evaluating adintrevimab for the prevention of COVID-19, which obligated the Company to make a $2.5 million milestone payment to Adimab. In August 2021, the Company achieved the third specified milestone under the agreement upon dosing of the first patient in a Phase 3 global clinical trial evaluating adintrevimab for the prevention of COVID-19, which obligated the Company to make a $4.0 million milestone payment to Adimab. The Company recognized each expense when achievement of each of the first, second and third milestones became probable of achievement in February, April and August 2021, respectively. The next potential milestone under the Adimab Assignment Agreement is a low-single-digit million dollar milestone related to the acceptance of the filing of the first New Drug Application for a Product, which was not considered probable as of June 30, 2022.

During the three and six months ended June 30, 2022, the Company did not recognize any in-process research and development ("IPR&D") expense in connection with contingent consideration payable under the Adimab Assignment Agreement. During the three and six months ended June 30, 2021, the Company recognized $2.5 million and $3.5 million, respectively, as IPR&D expense in connection with contingent consideration payable under the Adimab Assignment Agreement.

The Company is obligated to pay Adimab royalties of a mid-single-digit percentage based on net sales of any Products, once commercialized. The royalty rate is subject to reductions specified under the agreement. Royalties are due on a Product-by-Product and country-by-country basis beginning upon the first commercial sale of each Product and ending on the later of (i) 12 years after the first commercial sale of such Product in such country and (ii) the expiration of the last valid claim of a patent covering such Product in such country ("Royalty Term"). In addition, the Company is obligated to pay Adimab royalties of a specified percentage in the range of 45% to 55% of any compulsory sublicense consideration received by the Company in lieu of certain royalty payments. Except for the first milestone payment of $1.0 million, the second milestone payment of $2.5 million and the third milestone payment of $4.0 million, which were paid by the Company to Adimab in March, May and September 2021, respectively, no other milestone, royalty or other contingent payments had become due to Adimab through June 30, 2022.

Unless earlier terminated, the Adimab Assignment Agreement remains in effect until the expiration of the last-to-expire Royalty Term for any and all Products. The Company may terminate the agreement at any time for any or no reason upon advance written notice to Adimab, or in the event of a material breach by Adimab that is not cured with specific periods. Adimab may only terminate the agreement for an uncured material breach by the Company for its due diligence obligation or a payment obligation. Upon any termination of the agreement prior to its expiration, all licenses and rights granted pursuant to the arrangement will automatically terminate and revert to the granting party and all other rights and obligations of the parties will terminate.

The Company concluded that the Adimab Assignment Agreement represented an asset acquisition of IPR&D assets with no alternative future use. The arrangement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in a single asset. Therefore, the aggregate acquisition cost of $39.9 million was recognized as acquired IPR&D expense in July 2020. The $39.9 million of costs to acquire the IPR&D assets was determined as a result of the Company's allocation of the $40.0 million aggregate fair value of the 5,000,000 shares of the Series A Preferred Stock that the Company issued to Adimab on the acquisition date in exchange for (i) the IPR&D assets acquired from Adimab and (ii) 21,250,000 shares of the Company's common stock that it repurchased from Adimab on that same date. The Company allocated the $40.0 million fair value of the 5,000,000 shares of Series A Preferred Stock to the IPR&D assets and to the repurchased common stock based on their relative fair values on the acquisition date. As of that date and before allocation, the Company determined that the fair value of the repurchased common stock was $85,000, based on the results of a third-party valuation, and that the fair value of the IPR&D assets was $40.0 million. The Company determined the fair value of the 5,000,000 shares of Series A Preferred Stock based on the $8.00 price per share paid for the stock by new investors in the Company's Series A Preferred Stock financing, which closed on the same date as the date on which the Company acquired the CoV Antibodies and Adimab CoV Assets under the Adimab Assignment Agreement.

Adimab Collaboration Agreement

In May 2021, the Company entered into a Collaboration Agreement with Adimab (the "Adimab Collaboration Agreement") for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the Adimab Collaboration Agreement, the Company and Adimab will collaborate on research programs for a specified number of targets selected by the Company within a specified time period. Under the Adimab Collaboration Agreement, Adimab granted the Company a worldwide, non-exclusive license to certain of its platform patents and technology and antibody patents to perform the Company's responsibilities during the ongoing research period and for a specified evaluation period thereafter (the "Evaluation Term"). In addition, the Company granted Adimab a license to certain of the Company's patents and intellectual property solely to perform Adimab's responsibilities under the research plans. Under the Adimab Collaboration Agreement, the Company has an exclusive option, on a program-by-program basis, to obtain licenses and assignments to commercialize selected products containing or comprising antibodies directed against the applicable target, which option may be exercised upon the payment of a specified option fee for each program. Upon exercise of an option by the Company, Adimab will assign to the Company all right, title and interest in the antibodies of the optioned research program and will grant the Company a worldwide, royalty-free, fully paid-up, non-exclusive, sublicensable license under the Adimab platform technology for the development, manufacture and commercialization of the antibodies for which the Company has exercised its options and products containing or comprising those antibodies. The Company is obligated to use commercially reasonable efforts to develop, seek marketing approval for, and commercialize one product that contains an antibody discovered in each optioned research program.

The Company is obligated to pay Adimab a quarterly fee of $1.3 million, which may be cancelled at the Company's option at any time. For so long as the Company is paying such quarterly fee (or earlier if (i) the Company experiences a change of control after the third anniversary of the Adimab Collaboration Agreement or (ii) Adimab owns less than a specified percentage of the Company's equity), Adimab and its affiliates will not assist or direct certain third parties to discover or optimize antibodies that are intended to bind to coronaviruses or influenza viruses. The Company may also elect to decrease the scope of Adimab's exclusivity obligations and obtain a corresponding decrease in the quarterly fee. During the three and six months ended June 30, 2022, the Company recognized $1.3 million and $2.6 million, respectively, of research and development expense related to the quarterly fee. During the three and six months ended June 30, 2021, the Company did not recognize research and development expense related to the quarterly fee.

For each agreed upon research program that is commenced, the Company is obligated to pay Adimab quarterly for its services performed during a given research program at a specified full-time equivalent rate; a discovery delivery fee of $0.2 million; and an optimization completion fee of $0.2 million. For each option exercised by the Company to commercialize a specific research program, the Company is obligated to pay Adimab an exercise fee of $1.0 million. Amounts paid with respect to services performed by Adimab on the Company's behalf in each of the research programs under the Adimab Collaboration Agreement are recognized as research and development expense as such amounts are incurred and services are rendered. During the three and six months ended June 30, 2022, the Company recognized $0.6 million and $1.0 million, respectively, of expense in connection with services provided by Adimab. Through June 30, 2022, the Company recognized $0.2 million of research and development expense related to a drug delivery fee. Additionally, through June 30, 2022, the Company has not paid an optimization completion fee to Adimab, and the Company has not exercised its option with respect to any program.

The Company is obligated to pay Adimab up to $18.0 million upon the achievement of specified development and regulatory milestones for each product under the Adimab Collaboration Agreement that achieves such milestones. The next potential milestone under the Adimab Collaboration Agreement is a low-single-digit million milestone related to dosing of the first subject in a Phase 1 trial, which was not considered probable as of June 30, 2022. The Company is also obligated to pay Adimab royalties of a mid-single-digit percentage based on net sales of any product under the Adimab Collaboration Agreement, subject to reductions for third-party licenses. The royalty term will expire for each product on a country-by-country basis upon the later of (i) 12 years after the first commercial sale of such product in such country and (ii) the expiration of the last valid claim of any patent claiming composition of matter or method of making or using any antibody identified or optimized under the Adimab Collaboration Agreement in such country.

In addition, the Company is obligated to pay Adimab for Adimab's performance of certain validation work with respect to certain antigens acquired from a third party. In consideration for this work, the Company is obligated to pay Adimab royalties of a low single-digit percentage based on net sales of products that contain such antigens for the same royalty term as antibody-based products, but the Company is not obligated to make any milestone payments for such antigen products. Through June 30, 2022, the Company had not paid any royalties to Adimab under the Adimab Collaboration Agreement.

The Adimab Collaboration Agreement will expire (i) if the Company does not exercise any option, upon the conclusion of the last Evaluation Term for the research programs, or (ii) if the Company exercises an option, on the expiration of the last royalty term for a product in a particular country, unless the agreement is earlier terminated. The Company may terminate the Adimab Collaboration Agreement at any time upon advance written notice to Adimab. In addition, subject to certain conditions, either party may terminate the Adimab Collaboration Agreement in the event of a material breach by the other party that is not cured within specified periods. The Company concluded that the Adimab Collaboration Agreement represented an asset acquisition of IPR&D with no alternative future use. Therefore, payments made by the Company to Adimab for milestones achieved will be recognized as acquired IPR&D expense in the related period in which the services are performed or the related milestone is considered probable of achievement. Amounts paid with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement are recognized as research and development expense as such amounts are incurred and services are rendered. Please refer to Note 15 for additional information.

WuXi Cell Line License Agreement

In December 2020, the Company entered into a Cell Line License Agreement with WuXi Biologics (Hong Kong) Limited ("WuXi") (the "Cell Line License Agreement"), under which WuXi granted to the Company a non-exclusive, non-transferable, worldwide, royalty-bearing, sublicensable license to certain of its intellectual property, including certain patent rights associated with a proprietary cell line developed by WuXi for the exploitation of certain recombinant antibodies developed using such proprietary cell line (each, a "Licensed Product"). Each Licensed Product generated under the arrangement will be produced from a transformed or transfected version of the proprietary cell line derived by WuXi (each of such transformed or transfected cell lines, a "Licensed Cell Line").

The Company paid an upfront fee of $0.2 million to WuXi upon completion of cell bank generation for the first Licensed Cell Line created under the Cell Line License Agreement. The Company is also obligated to pay royalties in the range of 0.3% to 0.5% to WuXi based on net sales of any Licensed Products manufactured by the Company or a third party on its behalf. However, if the Company uses WuXi to manufacture all of its commercial supplies for Licensed Products, no royalties would be owed by the Company to WuXi for net sales of Licensed Products. The Company has an option to buy out its royalty obligations on a Licensed Cell Line-by-Licensed Cell Line basis by making a one-time payment of $15.0 million to WuXi. Royalties are due on a Licensed Product-by-Licensed Product basis commencing on the date of the first commercial sale of the applicable product and continuing for so long as the Company commercializes Licensed Products or, if earlier, until the Company exercises its option to buy out the royalty obligations. Through June 30, 2022, no royalties had become due to WuXi.

The Cell Line License Agreement remains in effect until it is terminated. The Company may terminate the Cell Line License Agreement at any time with notice to WuXi. WuXi may terminate the Cell Line License Agreement in the event the Company fails to make a payment when due under the Cell Line License Agreement and such non-payment is not cured within a specified period after notice. Either party may terminate the Cell Line License Agreement in the event of a material breach by the other party that is not cured within a specified period after notice. Upon termination of the Cell Line License Agreement, the license conveyed by WuXi to the Company will continue in full force and effect with respect to all Licensed Products manufactured using the Licensed Cell Line already generated under the Cell Line License Agreement, provided that the Company continues to pay its royalty obligations, if any.

The Company concluded that the Cell Line License Agreement represented an asset acquisition of IPR&D with no alternative future use. The Cell Line License Agreement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in a single asset. Therefore, the aggregate acquisition cost of $0.2 million, consisting solely of the upfront fee, was recognized as acquired IPR&D expense for the period from June 3, 2020 (inception) to December 31, 2020.

Research Collaboration and License Agreement with The Scripps Research Institute

In August 2021, the Company entered into a Research Collaboration and License Agreement (the "Research Agreement") with The Scripps Research Institute ("TSRI"). Under the terms of the Research Agreement, TSRI performed research activities (the "Research Program") to identify vaccine candidates for the prevention, diagnosis or treatment of influenza or beta coronaviruses. In August 2021, the Company paid TSRI $1.5 million in funding, which was credited against research funding payable by the Company under the Research Agreement.

In April 2022, the Company provided written notice to TSRI to terminate the Research Agreement. Following early termination in the second quarter of 2022, all licenses were terminated and reverted to TSRI.

Amounts incurred for services performed by TSRI under the Research Agreement were expensed to research and development expense as the services were rendered. During the three and six months ended June 30, 2022, the Company recognized $0.8 million and $1.7 million, respectively, of expense associated with services performed under the Research Agreement.

8. Commitments and Contingencies

Operating Lease Commitments

In September 2021, the Company entered into a five year noncancelable facilities lease agreement for approximately 9,600 square feet of office space in Waltham, Massachusetts. The monthly rental payments under the lease, which include base rent charges of $0.4 million per year, are subject to periodic rent increases through September 2026. In addition to base rent, monthly rental payments include the Company's proportionate share of operating expenses. The lease terms provide for one five-year extension term with base rent calculated on the then-market rate.

In June 2022, the Company entered into a two year noncancelable agreement for dedicated laboratory and office space in Newton, Massachusetts. The monthly rental payments under the agreement include base rent charges of $0.7 million per year. The agreement terms provide for a month-to-month extension with base rent calculated on the then-market rate with three months provided notice.

The components of operating lease expense were as follows (in thousands):

	For the Three Months Ended June 30, 2022	For The Six Months Ended June 30, 2022
Lease cost:		
Operating lease cost	$ 161	$ 266
Variable lease cost	8	16
Total lease cost	$ 169	$ 282
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows related to operating leases	$ 176	$ 276

Future minimum lease payments under the noncancelable leases as of June 30, 2022 was as follows (in thousands):

Year Ending December 31,	Operating Lease
2022 (excluding the six months ended June 30, 2022)	$ 553
2023	1,113
2024	713
2025	430
2026	328
Total lease payments	3,137
Present value adjustment	(279)
Present value of operating lease liability	$ 2,858

As of June 30, 2022, the Company's operating lease was measured using a weighted-average incremental borrowing rate of 6.0% over a weighted-average remaining lease term of 3.2 years.

The total operating liabilities are presented on the Company's condensed consolidated balance sheet based on maturity dates. $1.0 million of the total operating liabilities is classified under "operating lease liabilities, current" for the portion due within twelve months, and $1.9 million is classified under "operating lease liabilities, non-current".

License Agreements

The Company has entered into license agreements with Adimab, WuXi and TSRI (see Note 7). In April 2022, the Company provided written notice to TSRI to terminate the Research Agreement, and the Research Agreement was subsequently terminated during the second quarter of 2022.

Manufacturing Agreements

In December 2020, the Company entered into a Commercial Manufacturing Services Agreement with WuXi, which was amended and restated in August 2021 (as amended and restated, the "Commercial Manufacturing Agreement"). The Commercial Manufacturing Agreement outlines the terms and conditions under which WuXi manufactures adintrevimab drug substance and drug product for commercial use.

The Company committed to minimum noncancelable purchase obligations related to batches of adintrevimab drug substance and certain services with respect to the product requirements for 2022 and 2023 and batches of adintrevimab drug product and certain services with respect to the product requirements for 2022, the payments for which will extend into 2023.

In April 2022, the total volume of contractually binding drug substance and drug product batches to be manufactured under the Commercial Manufacturing Agreement was reduced to $51.6 million, a decrease of $107.8 million from the previous commitment of

minimum non-cancelable purchase obligations of $159.4 million. In addition, the Company received a credit in the low eight-figures to offset future services rendered by WuXi.

As of June 30, 2022, the Company had paid an aggregate of $19.6 million under the Commercial Manufacturing Agreement, which consisted of deposits paid related to the original minimum purchase obligations under the Commercial Manufacturing Agreement. In conjunction with the reduction described above, the Company received a $13.8 million credit related to the deposits previously paid for the cancelled batches.

Of the $19.6 million paid, $5.8 million was related to deposits for batches that were not cancelled, of which $2.4 million remained in prepaid expenses and other current assets as of June 30, 2022. The remaining $13.8 million was related to deposits for cancelled batches, which was applied to accrued expenses to offset payment of other WuXi services.

In August 2022, the low eight-figure credit was applied to WuXi-related services as a reduction of research and development expenses and a reduction of accrued expenses.

Unless earlier terminated, the Commercial Manufacturing Agreement remains in effect for an initial period of five years and thereafter automatically renews for further successive periods of five years each. Either party may terminate the agreement upon the breach or default by the other party, other than a non-payment breach, that is not cured within 90 days after notice. Both parties are also entitled to terminate the Commercial Manufacturing Agreement if the other party becomes insolvent or is the subject of a petition in bankruptcy or of any other related proceeding or event. Either party may terminate either the Commercial Manufacturing Agreement in its entirety, or an individual order, (i) to the extent the other party suffers a force majeure event that is continuing for a predefined period of time and (ii) if the other party fails to make a payment when due under the arrangement and such non-payment is not cured within 30 days after notice.

Other Contracts

The Company enters into agreements with third parties during the ordinary course of business for various products and services, including those related to research, preclinical and clinical operations, manufacturing and support, supply chain, and distribution. These contracts do not contain any material minimum purchase commitments. Certain of these agreements provide for termination rights subject to the payment of termination fees and/or wind-down costs. Under such agreements, the Company is contractually obligated to make certain payments to vendors upon early termination, primarily to reimburse them for their unrecoverable outlays incurred prior to cancellation as well as any amounts owed by the Company prior to early termination. The actual amounts the Company could pay in the future to the vendors under such agreements may differ from the purchase order amounts due to cancellation provisions. The termination fees were not probable of payment as of June 30, 2022 and December 31, 2021.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and estimated exposure amount. Legal fees and other costs associated with such proceedings are expensed as incurred. As of June 30, 2022 and December 31, 2021, the Company was not a party to any material legal proceedings.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to its vendors, lessors, contract research organizations, contract manufacturing organizations, business partners and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments that the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

9. Convertible Preferred Stock

The Company has issued Series A convertible preferred stock (the “Series A Preferred Stock”), Series B convertible preferred stock (the “Series B Preferred Stock”), and Series C Preferred Stock (the “Series C Preferred Stock”), all of which are collectively referred to as the “Preferred Stock.”

In July 2020, the Company issued and sold 6,237,500 shares of Series A Preferred Stock, at a price of $8.00 per share, for gross proceeds of $49.9 million and incurred $0.2 million of issuance costs. Concurrently, the Company issued 5,000,000 shares of Series A Preferred Stock to Adimab as consideration payable pursuant to the Adimab Assignment Agreement (see Note 7).

In October and November 2020, the Company issued and sold 1,410,434 shares of Series B Preferred Stock, at a price of $56.72 per share, for gross proceeds of $80.0 million and incurred $0.2 million of issuance costs. Adimab, a related party, participated in the Series B Preferred Stock financing by purchasing 44,076 shares of Series B Preferred Stock for an aggregate purchase price of $2.5 million. The issuance of the Series B Preferred Stock resulted in changes to certain terms of the Series A Preferred Stock. The Company

concluded that such changes were not significant and resulted in a modification, rather than an extinguishment, of the Series A Preferred Stock. The changes to the terms of the Series A Preferred Stock did not result in incremental value to the stockholders. Therefore, there was no impact to the accounting for the Series A Preferred Stock.

In April 2021, the Company issued and sold 4,296,550 shares of its Series C Preferred Stock, at a price of $78.08578 per share, for aggregate gross proceeds of $335.5 million and incurred $0.3 million of issuance costs. Adimab, a related party, participated in the Series C Preferred Stock financing by purchasing 128,064 shares of Series C Preferred Stock for an aggregate purchase price of $10.0 million.

The terms of the Series C Preferred Stock were substantially the same as the terms of the Series A Preferred Stock and Series B Preferred Stock, except that the original issue price per share and the conversion price per share of the Series C Preferred Stock is $78.08578.

In July 2021, the Company filed an amended and restated certificate of incorporation, which increased the Company's authority to issue (i) 150,000,000 shares of common stock and (ii) 16,944,484 shares of Preferred Stock. In August 2021, in connection with the closing of the IPO, the Company filed an amended and restated certificate of incorporation to, among other things: (i) increase the number of authorized shares of common stock from 150,000,000 shares to 1,000,000,000 shares, (ii) eliminate all references to the previously existing series of convertible preferred stock and (iii) authorize 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company's board of directors in one or more series.

Upon issuance of each series of Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that such features did not require the Company to separately account for these features. The Company also concluded that no beneficial conversion feature existed on the issuance date of each series of Preferred Stock.

Upon the closing of the Company's IPO in August 2021, all shares of the Company's convertible preferred stock then outstanding converted into 84,722,420 shares of common stock (see Note 10).

10. Common Stock

The voting, dividend and liquidation rights of the holders of shares of the Company's common stock were subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth above and described in the Company's final prospectus related to the IPO filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act") on August 6, 2021.

In June 2020, the Company issued and sold 21,250,000 shares of its common stock to Adimab upon formation of the Company for $0.00002 per share. In July 2020, such shares of common stock were repurchased by the Company from Adimab contemporaneous with the execution of the Adimab Assignment Agreement, pursuant to which the Company acquired certain intellectual property rights in exchange for the issuance of 5,000,000 shares of its Series A Preferred Stock. As of June 30, 2022 and December 31, 2021 the 21,250,000 shares of common stock repurchased from Adimab were retired and redesignated as authorized but unissued shares of the Company's common stock. The fair value of the repurchased common stock was $0.004 per share, or $85,000 in the aggregate, as determined based on a third-party valuation (see Note 7).

In April 2021, the Company increased the number of shares of common stock authorized for issuance from 19,000,000 to 23,251,555 shares and increased the number of shares of preferred stock authorized for issuance from 12,647,934 to 16,944,484 shares, of which 4,296,550 shares were designated as Series C Preferred Stock.

As described in Note 9 above, in July 2021, the Company filed an amended and restated certificate of incorporation, which increased the Company's authority to issue 150,000,000 shares of common stock. In August 2021, in connection with the closing of the IPO, the Company filed an amended and restated certificate of incorporation to, among other things, increase the number of authorized shares of common stock from 150,000,000 shares to 1,000,000,000 shares.

As of June 30, 2022, the Company had reserved 44,428,175 shares of common stock for the exercise of outstanding stock options and the issuance of awards available for grant under the Company's 2020 Equity Incentive Plan, 2021 Equity Incentive Plan and 2021 Employee Stock Purchase Plan (see Note 11).

Treasury Stock

In April and May 2021, the Company retired an aggregate of 22,600,000 shares of common stock held in treasury. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

In November 2021, the Company repurchased 468,751 shares of unvested restricted common stock at the original purchase price upon a termination of service during the vesting period. As of December 31, 2021, the shares of common stock repurchased were recorded as treasury stock in the accompanying consolidated balance sheets and consolidated statements of convertible preferred stock and stockholders' equity (deficit) as such shares were not retired. The fair value of the repurchased common stock was insignificant.

In February and June 2022, the Company repurchased 1,158,089 and 992,648 shares of unvested restricted common stock, respectively, at the original purchase price upon a termination of service during the vesting period. The shares of common stock repurchased were recorded as treasury stock in the accompanying condensed consolidated balance sheets and consolidated statements of convertible preferred stock and stockholders' equity (deficit) as such shares were not retired. The fair value of the repurchased common stock was insignificant.

In March 2022, the Company retired an aggregate of 1,626,840 shares of common stock held in treasury. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

Stock Split

In July 2021, the Company effected a five-for-one stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 9). Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the Preferred Stock conversion ratios.

Initial Public Offering

In August 2021, the Company completed its IPO, pursuant to which it issued and sold 20,930,000 shares of its common stock at an initial public offering price of $17.00 per share, including 2,730,000 shares of its common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were approximately $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all of the shares of the Company's convertible preferred stock then outstanding converted into 84,722,420 shares of common stock. Upon the conversion of the convertible preferred stock, the Company reclassified the carrying value of the convertible preferred stock to common stock (at par value) and additional paid-in capital.

11. Stock-Based Compensation

2020 Equity Incentive Plan

The Company's 2020 Equity Incentive Plan (the "2020 Plan") provides for the Company to grant incentive stock options, non-qualified stock options, restricted stock awards, restricted stock units and other stock-based awards to employees, members of the board of directors and consultants. The 2020 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The board of directors may also delegate to one or more officers of the Company the power to grant awards to employees and certain officers of the Company. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee or any such officer if so delegated.

The exercise price for stock options granted may not be less than the fair market value of the Company's common stock on the date of grant, as determined by the board of directors, or at least 110% of the fair market value of the Company's common stock on the date of grant in the case of an incentive stock option granted to an employee who owns stock representing more than 10% of the voting power of all classes of stock as determined by the board of directors as of the date of grant. Prior to the IPO, the Company's board of directors determined the fair value of the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant. Stock options granted under the 2020 Plan expire after ten years and typically vest over a four-year period with the first 25% vesting upon the first anniversary of a specified vesting commencement date and the remainder vesting in 36 equal monthly installments over the succeeding three years, contingent on the recipient's continued employment or service. Certain awards of stock options permit the holders to exercise the option in whole or in part prior to the full vesting of the option in exchange for unvested shares of restricted common stock with respect to any unvested portion of the option so exercised.

As of June 30, 2022, there were 11,600,938 shares authorized to be issued upon the exercise of outstanding stock option grants and no shares reserved for future issuance under the 2020 Plan.

2021 Equity Incentive Plan

In July 2021, the Company's board of directors adopted, and its stockholders approved, the 2021 Equity Incentive Plan (the "2021 Plan"), which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's IPO. The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares reserved for issuance under the 2021 Plan was equal to 35,075,122, which is the sum of 11,413,572 new shares; plus the number of shares (not to exceed 23,661,550 shares), which represents (i) the number of shares that remained available for issuance under the 2020 Plan, at the time the 2021 Plan became effective, and (ii) any shares subject to outstanding stock options or other stock awards that were granted under the 2020 Plan that are forfeited, terminate, expire or are otherwise not issued. In addition, the number of shares of the Company's common stock reserved for issuance under the 2021 Plan will automatically increase on the first day of each calendar year, beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 5% of the shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the board of directors. On January 1, 2022, 5,539,145 shares of common stock were automatically added to the shares authorized for issuance under the 2021 Plan pursuant to the terms of the 2021 Plan. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by the Company under the 2021 Plan will be added back to the shares of common stock available for issuance under the 2021 Plan.

As of June 30, 2022, there were 43,085,402 shares authorized to be issued, which includes 23,149,318 shares reserved for future issuance under the 2021 Plan.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. Prior to its IPO in August 2021, the Company had been a private company. Due to the proximity to the IPO, the Company continues to lack sufficient company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant date fair value of stock options granted:

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Expected term (in years)	5.8	6.1	6.0	6.0
Expected volatility	74.6%	73.3%	72.7%	73.4%
Risk-free interest rate	3.1%	1.0%	2.0%	0.9%
Expected dividend yield	—%	—%	—%	—%

Stock Option Activity

The following table summarizes the Company's stock option activity since December 31, 2021:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	18,871,592	$ 10.15	9.3	$ 24,897
Granted	6,574,509	$ 6.01		
Exercised	(148,353)	$ 0.83		
Forfeited	(5,361,664)	$ 10.62		
Outstanding at June 30, 2022	19,936,084	$ 8.73	9.0	$ 6,972
Vested and expected to vest at June 30, 2022	19,936,084	$ 8.73	9.0	$ 6,972
Options exercisable at June 30, 2022	4,272,473	$ 6.12	8.4	$ 2,976

The weighted-average grant date fair value of stock options granted during the three and six months ended June 30, 2022 was $2.07 and $3.88, respectively, per share. The weighted-average grant date fair value of stock options granted during the three and six months ended June 30, 2021 was $6.75 and $5.96, respectively, per share.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair market value of the common stock for the options that were in the money at June 30, 2022 and December 31, 2021.

The total intrinsic value of stock options exercised was $0.3 million and $0.6 million for the three and six months ended June 30, 2022, respectively.

In July 2022, David Hering, M.B.A. was appointed as the Company's Chief Executive Officer and as a Class III director on the Board of Directors. In conjunction with Mr. Hering's appointment, he was granted a stock option to purchase 2,000,000 shares of common stock, which will vest monthly in equal installments over 48 months. Mr. Hering is also eligible to receive an additional stock option to purchase up to 1,000,000 shares of common stock (the "Additional Option Grant") if certain goals approved by the Board of Directors, on the recommendation of the Compensation Committee, are achieved on or prior to December 31, 2022, with such achievement to be determined by the Board of Directors, upon the recommendation of the Compensation Committee. If such performance goals are partially achieved on or prior to December 31, 2022, then Mr. Hering may receive a partial amount of the Additional Option Grant, with such partial amount to be determined by the Board of Directors, in its sole and absolute discretion. The Additional Option Grant would vest monthly in equal installments over a 48-month period commencing on the applicable grant date.

Early Exercise of Stock Options into Restricted Stock

The Company's restricted stock activity during the six months ended June 30, 2022 is solely due to shares of restricted common stock issued pursuant to the permitted early exercise of stock options. Shares of common stock issued upon exercise of unvested stock options are restricted and continue to vest in accordance with the original vesting schedule applicable to the associated stock option award. The Company has the right to repurchase any unvested shares of restricted common stock, at the original purchase price, upon any voluntary or involuntary termination of the service relationship during the vesting period.

A summary of the Company's unvested common stock from option early exercises that is subject to repurchase by the Company is as follows:

	Number of Shares
Unvested restricted stock at December 31, 2021	3,082,175
Issued	—
Vested	(450,995)
Repurchased	(2,150,737)
Unvested restricted stock at June 30, 2022	480,443

Proceeds from the early exercise of stock options are recorded as an early-exercise liability on the condensed consolidated balance sheets. The liability for unvested common stock subject to repurchase is then reclassified to common stock and additional paid-in capital as the Company's repurchase right lapses. Shares issued pursuant to the early exercise of stock options are not considered to be outstanding for accounting purposes until the shares vest. As of June 30, 2022 and December 31, 2021 the liability related to the payments for unvested shares from early-exercised options was less than $0.1 million.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense (service-based stock options and employee stock purchase plan) in the following expense categories of its condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Research and development	$ 3,382	$ 1,152	$ 6,535	$ 1,431
Selling, general and administrative	2,979	2,190	1,809	2,498
	$ 6,361	$ 3,342	$ 8,344	$ 3,929

In February 2022, Tillman U. Gerngross, Ph.D., resigned as Chief Executive Officer and President and as a member of the Company's board of directors. In accordance with his resignation, Dr. Gerngross's outstanding stock options were forfeited, resulting in a reversal of selling, general and administrative related stock-based compensation expense of approximately $4.6 million.

As of June 30, 2022, total unrecognized stock-based compensation expense related to unvested stock-based awards was $86.4 million, which is expected to be recognized over a weighted-average period of 3.0 years.

2021 Employee Stock Purchase Plan

In July 2021, the Company's board of directors adopted, and its stockholders approved, the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's IPO. A total of 1,342,773 shares of common stock were initially reserved for issuance under the 2021 ESPP. There were no shares issued under the 2021 ESPP as of June 30, 2022. The number of shares of common stock that may be issued under the 2021 ESPP will automatically increase on the first day of each calendar year, beginning on January 1, 2022 and continuing through January 1, 2031, by an amount equal to the lesser of (i) 1% of the shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, (ii) 2,685,546 shares and (iii) an amount determined by the Company's board of directors. The number of shares to be issued under the 2021 ESPP did not increase on January 1, 2022 as determined by the Company's board of directors. During the three and six months ended June 30, 2022, the Company recognized less than $0.1 million in related stock-based compensation expense.

12. Income Taxes

For the three and six months ended June 30, 2022 and 2021, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each period, due to its uncertainty of realizing a benefit from those items. All of the Company's operating losses since inception have been generated in the United States.

13. Defined Contribution Plan

The Company maintains a 401(k) Plan (the "401(k) Plan") for the benefit of eligible employees. The 401(k) Plan is a defined contribution plan under Section 401(k) of the Internal Revenue Code of 1986 that covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Pursuant to the terms of the 401(k) Plan, the Company is required to make non-elective contributions of 3% of eligible participants' compensation. For the three and six months ended June 30, 2022, the Company contributed $0.2 million and $0.4 million, respectively, to the 401(k) Plan. For the three and six months ended June 30, 2021, the Company contributed $0.1 million and $0.2 million, respectively, to the 401(k) Plan.

14. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Numerator:				
Net loss attributable to common stockholders	$ (50,990)	$ (44,673)	$ (151,656)	$ (83,373)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	108,166,890	249,769	108,019,051	125,574
Net loss per share attributable to common stockholders, basic and diluted	$ (0.47)	$ (178.86)	$ (1.40)	$ (663.94)

Shares of unvested restricted common stock are not considered outstanding for accounting purposes until vested and were excluded from the calculations of basic net loss per share attributable to common stockholders for all periods presented.

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated, because including them would have had an anti-dilutive effect:

	Three and Six Months Ended June 30,	
	2022	2021
Convertible preferred stock (as converted to common stock)	—	84,722,420
Stock options to purchase common stock	19,936,084	14,931,630
Unvested restricted common stock	480,443	4,194,930
	20,416,527	103,848,980

15. Related Party Transactions

Adimab participated in the Series B Preferred Stock financing and the Series C Preferred Stock financing by purchasing 44,076 and 128,064 shares of Series B Preferred Stock and Series C Preferred Stock, respectively, for an aggregate purchase price of $2.5 million and $10.0 million, respectively (see Note 9).

Adimab Assignment Agreement

Under the Adimab Assignment Agreement, Adimab, a principal stockholder of the Company, received upfront consideration in the form of Series A Preferred Stock, is entitled to receive milestone and royalty payments upon specified conditions, and receives payments from the Company for providing ongoing services under the agreement (see Note 7).

During the three and six months ended June 30, 2022, the Company did not recognize any IPR&D expense pursuant to the Adimab Assignment Agreement. During the three and six months ended June 30, 2021, the Company recognized $2.5 million and $3.5 million, respectively, as IPR&D expense in connection with milestones payable under the Adimab Assignment Agreement.

During the three and six months ended June 30, 2022, the Company recognized $0.2 million and $0.5 million, respectively, of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement. During the three and six months ended June 30, 2021, the Company recognized $0.2 million and $0.4 million, respectively, of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement.

Adimab Collaboration Agreement

Under the Adimab Collaboration Agreement, the Company is obligated to pay Adimab for certain fees, milestone and royalty payments (see Note 7).

During the three and six months ended June 30, 2022, the Company recognized $1.3 million and $2.6 million, respectively, of research and development expense related to the quarterly fee. During the three and six months ended June 30, 2021, the Company did not recognize research and development expense related to the quarterly fee.

During the three and six months ended June 30, 2022, the Company recognized $0.6 million and $1.0 million, respectively, of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement. During the three and six months ended June 30, 2021, the Company did not incur significant costs with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement.

During the three and six months ended June 30, 2022, the Company recognized $0.2 million of research and development expense related to a drug delivery fee.

As of June 30, 2022 and December 31, 2021, $1.0 million and $0.6 million, respectively, was due to Adimab under both the Adimab Assignment Agreement and the Adimab Collaboration Agreement by the Company. As of June 30, 2022 and December 31, 2021, no amounts were due from Adimab under the Adimab Assignment Agreement or the Adimab Collaboration Agreement to the Company.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission ("SEC") on March 31, 2022 (as subsequently amended by Amendment No. 1 to the Company's Annual Report on Form 10-K, filed with the SEC on April 29, 2022, the "2021 Form 10-K"). Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us," and "our" refer to Adagio Therapeutics, Inc. together with its consolidated subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include, but are not limited to, statements regarding our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, and are not guarantees of future performance. The words "may," "anticipate," "believe," "could," "expect," "intends," "might," "plan," "possible," "potential," "aim," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These statements speak only as of the date of this Quarterly Report on Form 10-Q and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about the following:

- the timing, progress and results of our preclinical studies and clinical trials of our current and future product candidates, including statements regarding the timing of our planned regulatory submissions, initiation and completion of studies or trials and related preparatory work and the period during which the results of the trials will become available, and our research and development programs;
- the timing of any submission of filings for regulatory approval of, and our ability to obtain and maintain regulatory approvals for, our current and future product candidates;
- our manufacturing capabilities and strategy, including the scalability and commercial viability of our manufacturing methods and processes;
- our ability to identify patients with the diseases treated by our product candidates and to enroll these patients in our clinical trials;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our product candidates, if approved for commercial use;
- our expectations regarding the scope of any approved indication for adintrevimab or any other product candidate;
- our ability to successfully commercialize our product candidates;
- our ability to leverage technology to identify and develop future product candidates;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for or ability to obtain additional funding before we can expect to generate any revenue from product sales;
- our belief that we have sufficient cash resources to fund our operating expenses and capital expenditure requirements into the second quarter of 2024;
- our competitive position and the development of and projections relating to our competitors or our industry; and
- business disruptions affecting our preclinical studies or the initiation, patient enrollment, development and operation of our clinical trials, including a public health crisis, such as the outbreak of COVID-19.

The foregoing list of forward-looking statements is not exhaustive. You should refer to the "Risk Factors" section of this Quarterly Report on Form 10-Q for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Other sections of this Quarterly Report on Form 10-Q may include additional factors that could harm our business and financial performance. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report on Form 10-Q will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained

herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks and other information we describe in the reports we file from time to time with the SEC.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Overview

Adagio Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of differentiated products for the prevention and treatment of infectious disease. We are developing our lead product candidate, adintrevimab, for the prevention and treatment of coronavirus disease 2019 ("COVID-19"), the disease caused by the virus SARS-CoV-2 and its variants. COVID-19 has caused the current global pandemic that remains a significant global health crisis and has resulted in millions of deaths and lasting health problems in many survivors. We believe that COVID-19 will become an endemic disease requiring a variety of effective, safe and convenient prevention and treatment options for years to come. We are leveraging our team's collective expertise and capabilities to deliver adintrevimab to patients and to discover novel solutions to infectious diseases through internal research and collaborations.

Adintrevimab is designed to be a potent, long-acting and broadly neutralizing antibody for both the prevention and treatment of COVID-19. We believe several key attributes combine to potentially differentiate adintrevimab, including breadth, potency, durability of protection, convenient intramuscular administration, and potential for broad application across multiple indications, depending on the SARS-CoV-2 variant.

Data from our Phase 1 healthy volunteer study ADG20-1-001 confirmed the extended half-life of adintrevimab, which we believe may allow for durable protection against COVID-19, depending on the variant. In February 2022, we expanded the Phase 1 study to evaluate safety and pharmacokinetics at higher doses. As of August 8, 2022, there were no study drug related adverse events, serious adverse events, injection-site reactions or hypersensitivity reactions reported across all dose levels evaluated.

We are assessing adintrevimab in two separate Phase 2/3 clinical trials: our EVADE trial to evaluate adintrevimab for the prevention of COVID-19 and our STAMP trial to evaluate adintrevimab for the treatment of COVID-19. Our EVADE clinical trial is a global Phase 2/3 clinical trial evaluating adintrevimab as a prevention for COVID-19 in both the post-exposure and pre-exposure settings. Our STAMP trial is our global Phase 2/3 clinical trial evaluating adintrevimab as a treatment for COVID-19. Due to the emergence and global spread of the Omicron variant, against which adintrevimab has reduced *in vitro* neutralization potency compared to prior variants, enrollment in both EVADE and STAMP was paused on January 11, 2022, and preliminary safety and efficacy data were evaluated.

In the primary analysis population, patients infected with or exposed to a non-Omicron variant (the "pre-Omicron group"), adintrevimab met the primary objectives across all three indications, demonstrating statistically significant and clinically meaningful efficacy. In pre-exposure and post-exposure prophylaxis, adintrevimab was associated with 71% and 75% relative risk reductions compared to placebo, respectively, in the prevention of reverse transcription-polymerase chain reaction ("RT-PCR") confirmed symptomatic COVID-19. In an exploratory analysis of patients exposed to the Omicron variant (the "post-Omicron group") in pre-exposure prophylaxis, adintrevimab was associated with a clinically meaningful reduction in the risk of developing RT-PCR confirmed symptomatic COVID-19 compared with placebo. In treatment, adintrevimab was associated with a 66% relative risk reduction compared to placebo in the incidence COVID-19 related hospitalization or all cause death through Day 29 in the pre-Omicron group. In patients treated within three days of symptom onset, adintrevimab was associated with a reduced risk of COVID-19 hospitalization or death from any cause through Day 29 by 74% compared to placebo. A preliminary analysis of available safety data in each trial revealed a safety profile similar to that of placebo for adintrevimab.

The Omicron BA.4 and BA.5 sublineages, which have shown reduced *in vitro* susceptibility to monoclonal antibodies, have recently emerged as the current predominant variants of SARS-CoV-2 in the United States. Adintrevimab, which has demonstrated broadly neutralizing activity *in vitro* against SARS-CoV-2 variants of concern including Alpha, Beta, Delta, Delta Plus, Gamma and Omicron BA.1, has markedly reduced neutralization activity *in vitro* against the Omicron BA.2, BA.4, and BA.5 sublineages. Based on feedback from the FDA regarding adintrevimab's lack of neutralizing activity against the BA.2 variant, we paused the submission of an Emergency Use Authorization ("EUA") request. We intend to continue engaging with the FDA and monitor the evolution of SARS-CoV-2 and the *in vitro* activity of adintrevimab against predominant variants in the United States to determine the optimal timing for the planned EUA request. In addition, we continue engaging with other health authorities outside of the United States on potential authorization pathways for adintrevimab.

We are committed to advancing adintrevimab as a potential future therapeutic option in anticipation of the emergence of new variants. We are on-track to have more than 700,000 doses of adintrevimab secured in 2022, in preparation of its potential utility as a prophylaxis and treatment option for COVID-19 in the future.

We are also evaluating additional broadly neutralizing antibodies targeting the receptor binding domain, as well as other subdomains within the spike protein for COVID-19. We are advancing proprietary antibodies targeting distinct sites with activity against all SARS-CoV-2 variants of concern ("VOCs") to date, including the Omicron variant and its sublineages, and plan to take a combination of these antibodies into clinical trials in the first quarter of 2023 for the prevention and treatment of COVID-19. In addition, we plan to leverage our robust antibody discovery and development capabilities and our partnerships that together have enabled our expedited advancement of adintrevimab into clinical trials to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and influenza. We continue to evaluate product candidates for infectious diseases with high unmet medical need through in-licensing opportunities that may leverage our team's expertise and capabilities.

SARS-CoV-2 has given rise to a global pandemic that swept rapidly throughout the world in 2020. Of significant current concern is the continued emergence of a number of SARS-CoV-2 variants with increased transmissibility, pathogenicity, and/or the ability to evade neutralizing antibodies. In addition to the emergence of these variants, there are multiple factors that we believe contribute to the likelihood of COVID-19 becoming an endemic threat, including: (1) viral transmission before symptom onset; (2) uneven global rollout of vaccinations; (3) ongoing vaccine hesitancy; (4) limited duration of immunity conferred by both natural infection and vaccination; (5) limited vaccine efficacy against certain SARS-CoV-2 variants; (6) uncertain impact of vaccines on transmission; and (7) variable implementation of virus mitigation behaviors, such as wearing masks and social distancing. We also believe that future pandemics similar to the COVID-19 pandemic are likely because, in many parts of the world, humans live in close proximity to animal species harboring coronaviruses that are capable of infecting humans.

Our vision is to discover, develop and commercialize differentiated products for the prevention and treatment of infectious diseases. To enable this vision, our current discovery efforts are focused on unique antibody-based product candidates that we optimize to improve breadth, potency, half-life, where applicable, and developability. Key elements that we believe differentiate our approach include: (1) recognition of the importance of and identification of broadly neutralizing antibodies; (2) industry-leading B cell mining, protein engineering and developability screening capabilities through our internal expertise and collaborations; and (3) reducing risk of clinical resistance.

We were formed in June 2020. In July 2020, we entered into an assignment and license agreement (the "Adimab Assignment Agreement"), with Adimab, pursuant to which we acquired certain rights to Adimab's antibodies relating to COVID-19 and severe acute respiratory syndrome ("SARS"), as well as related provisional patent applications, know-how and data generated with respect to the associated antibodies. In addition, Adimab granted to us a non-exclusive, worldwide license to certain of Adimab's platform patents and technology for use in research and development. In connection with the rights and license acquired, we issued 5,000,000 shares of our Series A Preferred Stock to Adimab. In May 2021, we entered into a funded discovery agreement with Adimab focused on discovery efforts for new antibodies that may be effective against other coronaviruses and influenza, both of which have the potential to cause pandemics. In the event that Adimab discovers an antibody that is expected to meet certain product profiles developed by us, we will have the exclusive option to require Adimab to assign us its rights in any such antibody and to grant us certain licenses. In addition, we engage other third parties to perform ongoing research and development and other services on our behalf.

Since our inception, we have devoted substantially all of our resources to organizing and staffing, building an intellectual property portfolio, business planning, conducting research and development, establishing and executing arrangements with third parties for the manufacture of our product candidates and raising capital. We rely heavily on partnerships, external consultants and contract research organizations ("CROs") to conduct our discovery, non-clinical, preclinical and clinical activities. Additionally, we are currently dependent on WuXi Biologics (Hong Kong) Limited ("WuXi"), a contract development and manufacturing organization ("CDMO"), for the manufacture of our product candidates for clinical and commercial use. We expect to continue to rely on third parties for clinical trials and the manufacture and testing of our product candidates.

Since our inception, we have financed our operations with net proceeds of $464.7 million from sales of our preferred stock, and most recently, with net proceeds from our initial public offering ("IPO"). In August 2021, we completed our IPO, pursuant to which we issued and sold 20,930,000 shares of our common stock, including 2,730,000 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. We received aggregate net proceeds from our IPO of $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us. To date, we have not generated any revenue from any sources, including product sales or government supply contracts. We have not yet commenced significant development activities with respect to other product candidates. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates, if approved.

Since our inception, we have incurred significant losses, including a net loss of $151.7 million for the six months ended June 30, 2022. As of June 30, 2022, we had an accumulated deficit of $443.8 million. We expect to continue to incur significant expenses and recognize losses in the foreseeable future as we expand and progress our research and development activities as well as the associated manufacturing activities and commercialization efforts. In addition, our losses from operations may fluctuate significantly from period to period depending on the timing of our clinical trials and our expenditures on other research and development activities, including any associated manufacturing activities, and potential commercialization efforts. Our expenses could increase substantially in connection with our ongoing activities, as we:

- continue to conduct our ongoing clinical trials of adintrevimab, as well as initiate and complete additional clinical trials of future product candidates or current product candidates in new indications or patient populations;
- continue to advance the preclinical development of our other product candidates and our preclinical and discovery programs, including any modification of adintrevimab and development and screening of additional antibodies;
- seek regulatory approval for any product candidates that successfully complete clinical trials;
- pursue marketing approvals or EUA and reimbursement for our product candidates;
- acquire or in-license other product candidates, intellectual property and/or discovery technologies;
- validate our commercial-scale current good manufacturing practices ("cGMP") manufacturing process;
- manufacture material under cGMP at our contracted manufacturing facilities for clinical trials and potential EUA, regulatory approval and commercial sales;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- comply with regulatory requirements established by the applicable regulatory authorities;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval or EUA;
- hire and retain additional personnel, including research, clinical, development, manufacturing, quality control, quality assurance, regulatory and scientific personnel;
- add operational, financial, corporate development, management information systems and administrative personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

We do not anticipate generating revenue from product sales, including government supply contracts, unless and until we successfully complete clinical development and obtain marketing approvals or EUA for one or more of our product candidates. We are currently establishing our commercial infrastructure to support the anticipated marketing and distribution of our product candidates. Subject to receiving marketing approval or EUA for any of our product candidates for the prevention and/or treatment of COVID-19, we expect to enter into arrangements with third parties for the sale, marketing and distribution of our product candidates. Accordingly, if we obtain marketing approval or EUA for any of our product candidates, we will incur significant additional commercialization expenses related to product manufacturing, marketing, sales and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, government or private-party grants, debt financings, collaborations with other companies and strategic alliances. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and emergence of adintrevimab susceptible SARS-CoV-2 VOCs, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. We may never obtain regulatory approval for any of our product candidates. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Based on our current operating plan, we believe that our existing cash and cash equivalents of $474.9 million as of June 30, 2022, will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources."

Impact of COVID-19 on Our Operations

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. The evolving and constantly changing impact of the pandemic will directly affect the potential commercial prospects of adintrevimab and other product candidates for the prevention and treatment of COVID-19. The severity of the COVID-19 pandemic and the continued emergence of VOCs (such as the widespread Omicron variant and its sublineages and the Delta variant), the availability, administration and acceptance of vaccines, monoclonal antibodies, antiviral agents and other therapeutic modalities, vaccine mandates by employers and/or local or

national governments, and the potential development of "herd immunity" by the global population will affect the design and enrollment of our clinical trials, the potential regulatory authorization or approval of our product candidates and the commercialization of our product candidates, if approved.

In addition, our business and operations may be more broadly adversely affected by the COVID-19 pandemic. The COVID-19 outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen. The global COVID-19 pandemic continues to evolve rapidly, and we will continue to monitor it closely. The ultimate extent of the impact of the COVID-19 pandemic on our business, financial condition, operations and product development timelines and plans remains highly uncertain and will depend on future developments, including the duration and spread of outbreaks and the continued emergence of variants, its impact on our clinical trial design and enrollment, trial sites, CROs, CDMOs, and other third parties with which we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. To date, we have experienced some delays and disruptions in our development activities as a result of the COVID-19 pandemic. Some of our CROs, CDMOs and other service providers also continue to be impacted. We will continue to monitor developments as we address the disruptions, delays and uncertainties relating to the COVID-19 pandemic. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, our results and operations may be materially adversely affected and may affect our ability to raise capital.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales, including government supply contracts, or any other sources. If our development efforts for our product candidates are successful and result in regulatory approval or collaboration or license agreements with third parties, we may generate revenue in the future from product sales or payments from collaboration or license agreements that we may enter into with third parties, or any combination thereof.

Research and Development Expenses

The nature of our business and primary focus of our activities generates a significant amount of research and development costs. Research and development expenses represent costs incurred by us for:

- the non-clinical and preclinical development of our product candidates, including our discovery efforts;
- the procurement of our product candidates from third-party manufacturers; and
- the global clinical development of our product candidates.

Such costs consist of:

- personnel-related expenses, including salaries, bonuses, benefits and other compensation-related costs, including stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred under agreements with third parties, such as collaborators, consultants, contractors and CROs, that conduct the discovery, non-clinical and preclinical studies and clinical trials of our product candidates and research programs;
- costs of procuring manufactured product candidates for use in non-clinical studies, preclinical studies and clinical trials from third-party CDMOs;
- costs of outside consultants and advisors, including their fees and stock-based compensation;
- laboratory-related expenses, which include laboratory supplies, rent expense and other operating costs;
- payments made under third-party licensing agreements; and
- other expenses incurred as a result of research and development activities.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Our primary focus since inception has been the development of adintrevimab. Our research and development costs consist primarily of external costs, such as fees paid to CDMOs, CROs and consultants in connection with our non-clinical studies, preclinical studies and clinical trials. To date, external research and development costs for any individual product candidate have been tracked

commencing upon product candidate nomination. We do not allocate employee-related costs, costs associated with our discovery efforts and other internal or indirect costs to specific research and development programs or product candidates because these resources are used and these costs are deployed across multiple programs under development and, as such, are not separately classified.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher and more variable development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Our research and development expenses could increase substantially in the near term as we advance adintrevimab through clinical development on a global basis, if required, pursue regulatory approval of adintrevimab, advance additional antibody candidates into clinical trials, continue to discover and develop additional product candidates and incur expenses associated with hiring additional personnel to support our research and development efforts, including the associated manufacturing activities.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of our product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- filing acceptable investigational new drug applications with the FDA or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials, manufacture the product candidates and complete associated regulatory activities;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and successfully develop, obtain regulatory approval or EUA for our product candidates;
- successful enrollment and timely completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- the costs associated with the development of any additional development programs and product candidates we identify in-house or acquire through collaborations;
- the prevalence, nature and severity of adverse events experienced with adintrevimab or any other product candidates;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trademark and trade secret protection and regulatory exclusivity for our product candidates, if and when approved, and otherwise protecting our rights in our intellectual property portfolio;
- receipt of timely marketing approvals from applicable regulatory authorities;
- our ability to maintain compliance with regulatory requirements, including good clinical practices, current good laboratory practices and cGMPs, and to comply effectively with other rules, regulations and procedures applicable to the development and sale of pharmaceutical products;
- potential significant and changing government regulation, regulatory guidance and requirements and evolving treatment guidelines; and
- the impact of any business interruptions to our operations or those of third parties with which we work, particularly in light of the current COVID-19 pandemic.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. We may never succeed in obtaining regulatory approval or EUA for any of our product candidates. In addition, in the absence of a declaration by the U.S. Department of Health and Human Services of a federal public health emergency (a "Public Health Emergency"), we will not be able to receive an EUA. The declaration of a Public Health Emergency has recently been extended to mid-October 2022 and may or may not be renewed again.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development ("IPR&D") expenses consist primarily of the upfront costs we incurred in July 2020, as well as any costs of contingent milestone payments we incurred in subsequent periods, to acquire rights to Adimab's antibodies

relating to COVID-19 and SARS and related intellectual property and a license to certain of Adimab's platform patents and technology, or the IPR&D assets, for use in the research and development of our product candidates. We expensed the cost of the IPR&D assets because they had no alternative future use as of the acquisition date. We will recognize additional acquired IPR&D expenses in the future if and when it is deemed probable that we will make contingent milestone payments to Adimab under the terms of the agreement by which we acquired the IPR&D assets.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, bonuses, benefits, third-party fees and other related costs, including stock-based compensation, for our personnel and external contractors involved in our executive, finance, legal, business development and other administrative functions, as well as our commercial function. Selling, general and administrative expenses also include costs incurred for outside services associated with such functions, including legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; market research costs; and other selling, general and administrative expenses. These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

Our selling, general and administrative expenses could increase in the future as our business expands and we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates. In particular, we could incur additional commercialization expenses prior to any regulatory approval or EUA of our product candidates as we continue to expand our commercial function to support potential future product launches. We also anticipate that we will continue to incur increased expenses associated with operating as a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services, director and officer insurance premiums, and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file additional patent applications to protect innovations arising from our research and development activities.

In June 2022, we entered into a two year noncancelable agreement for laboratory and office space in Newton, MA for research and development purposes. Through June 30, 2022, we have operated as a virtual company and maintained a corporate headquarters for general and administrative purposes only. Therefore, we did not incur material operating expenses for the rent, maintenance and insurance of facilities, or for depreciation of fixed assets.

Other Income (Expense), Net

Other income (expense), net consists of interest income earned from our cash, cash equivalents and marketable securities and the net amortization or accretion of premiums and discounts related to our marketable securities. We expect our interest income to vary each reporting period depending on our average bank deposits, money market funds and investment balances during the period and market interest rates.

Income Taxes

Since our inception, we have not recorded any income tax expense or realized benefits for the net losses we have incurred or for the research and development tax credits generated in each period as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss ("NOL") carryforwards and tax credit carryforwards will not be realized.

Results of Operations

Comparison of the three months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021:

(in thousands)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Change
Operating expenses:			
Research and development	$ 37,129	$ 35,067	$ 2,062
Acquired in-process research and development	—	2,500	(2,500)
Selling, general and administrative	14,620	7,124	7,496
Total operating expenses	51,749	44,691	7,058
Loss from operations	(51,749)	(44,691)	(7,058)
Other income (expense):			
Other income (expense), net	759	18	741
Total other income (expense), net	759	18	741
Net loss	$ (50,990)	$ (44,673)	$ (6,317)

The following discussion presents the components of our expenses for the periods presented:

Research and Development Expenses

(in thousands)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Change
Direct, external research and development expenses by program:			
Adintrevimab	$ 23,213	$ 28,031	$ (4,818)
Unallocated research and development expenses:			
Personnel-related costs	9,197	5,340	3,857
External discovery-related and other costs	4,719	1,696	3,023
Total research and development expenses	$ 37,129	$ 35,067	$ 2,062

Research and development expenses were $37.1 million for the three months ended June 30, 2022, compared to $35.1 million for the three months ended June 30, 2021. The $2.0 million increase in research and development expenses was primarily due to the following:

- The decrease in direct costs related to our adintrevimab program of $4.8 million was primarily due to a decrease in our contract manufacturing and contract research expenses of $5.1 million related to the production of materials for use in our clinical trials and nonclinical studies for the adintrevimab program, as well as supply for use under a potential EUA for adintrevimab, procured from WuXi, our sole-source supplier of drug substance and drug product, and a decrease in other external research and development costs of $0.3 million. This was offset by an increase in our clinical trial expenses of $0.6 million related to ongoing monitoring activities for our clinical trials for the adintrevimab program, partially offset by lower costs due to a continued pause in trial enrollment during the three months ended June 30, 2022.
- Personnel-related costs, including salaries, bonuses, benefits and other compensation-related costs were $5.8 million and stock-based compensation expense was $3.4 million for the three months ended June 30, 2022, compared to personnel-related costs of $4.1 million and stock-based compensation expense of $1.2 million for the three months ended June 30, 2021. The increase in personnel-related costs of $3.9 million was primarily due to the hiring of additional individuals to support the development of our product candidates, including an increase in stock-based compensation expense of $2.2 million.
- The increase in external discovery-related and other costs of $3.0 million was primarily due to the $1.3 million quarterly fee under the Adimab Collaboration Agreement, $0.8 million with respect to services performed and other fees under the Adimab Assignment Agreement and the Adimab Collaboration Agreement, and $0.9 million in other external costs, including consulting services, insurance costs and software expenditures. We did not pay a quarterly fee to Adimab under the Adimab Collaboration Agreement during the three months ended June 30, 2021.

Acquired In-Process Research and Development Expenses

There was no IPR&D expense recognized during the three months ended June 30, 2022.

Acquired IPR&D expenses of $2.5 million for the three months ended June 30, 2021 consisted of the cost we incurred in the period under the Adimab Assignment Agreement for a milestone payment that became due to Adimab in April 2021 upon the dosing of the first patient in a Phase 2 clinical trial evaluating adintrevimab for the prevention of COVID-19. The amount of this contingent payment was recognized as an IPR&D expense based on the nature of the associated assets acquired from Adimab on the date the milestone achievement became probable.

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Change
Personnel-related costs	$ 5,784	$ 4,054	$ 1,730
Professional and consultant fees	8,245	2,949	5,296
Other	591	121	470
Total selling, general and administrative expenses	$ 14,620	$ 7,124	$ 7,496

Selling, general and administrative expenses were $14.6 million for the three months ended June 30, 2022, compared to $7.1 million for the three months ended June 30, 2021. The $7.5 million increase in selling, general and administrative expenses was primarily due to the following:

- Personnel-related costs, including salaries, bonuses, benefits and other compensation-related costs were $2.8 million and stock-based compensation expense was $3.0 million for the three months ended June 30, 2022, compared to

personnel-related costs of $1.9 million and stock-based compensation expense of $2.2 million for the three months ended June 30, 2021. The increase in personnel-related costs of $1.7 million was primarily due to the hiring of additional individuals to support our operations as we began operating as a public company, including an increase in stock-based compensation expense of $0.8 million.

- The increase in professional services and consultant fees of $5.3 million was primarily due to costs incurred as we began operating as a public company, including expenses related to corporate governance matters, director and officer insurance premiums, audit and other fees.
- Other costs remained relatively consistent between periods.

Other Income (Expense), Net

Other income (expense), net was $0.8 million and less than $0.1 million for the three months ended June 30, 2022 and 2021, respectively, consisting primarily of interest earned on invested cash balances.

Comparison of the six months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021:

(in thousands)	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021	Change
Operating expenses:			
Research and development	$ 129,164	$ 69,204	$ 59,960
Acquired in-process research and development	—	3,500	(3,500)
Selling, general and administrative	23,324	10,695	12,629
Total operating expenses	152,488	83,399	69,089
Loss from operations	(152,488)	(83,399)	(69,089)
Other income (expense):			
Other income (expense), net	832	26	806
Total other income (expense), net	832	26	806
Net loss	$ (151,656)	$ (83,373)	$ (68,283)

The following discussion presents the components of our expenses for the periods presented:

Research and Development Expenses

(in thousands)	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021	Change
Direct, external research and development expenses by program:			
Adintrevimab	$ 100,796	58,683	$ 42,113
Unallocated research and development expenses:			
Personnel-related costs	18,709	7,601	11,108
External discovery-related and other costs	9,659	2,920	6,739
Total research and development expenses	$ 129,164	$ 69,204	$ 59,960

Research and development expenses were $129.2 million for the six months ended June 30, 2022, compared to $69.2 million for the six months ended June 30, 2021. The $60.0 million increase in research and development expenses was primarily due to the following:

- The increase in direct costs related to our adintrevimab program of $42.1 million was primarily due to overall increases in our contract manufacturing and contract research expenses of $28.5 million related to the production of materials for use in our clinical trials and nonclinical studies for the adintrevimab program, as well as supply for use under a potential EUA for adintrevimab, procured from WuXi, our sole-source supplier of drug substance and drug product, and clinical trial expenses of $14.4 million related to ongoing activities for our clinical trials for the adintrevimab program, partially offset by lower costs due to a pause in trial enrollment during the six months ended June 30, 2022. These overall increases were offset by a decrease in other external research and development costs of $0.8 million.
- Personnel-related costs, including salaries, bonuses, benefits and other compensation-related costs were $12.2 million and stock-based compensation expense was $6.5 million for the six months ended June 30, 2022, compared to personnel-related costs of $6.2 million and stock-based compensation expense of $1.4 million for the six months ended June 30, 2021. The

increase in personnel-related costs of $11.1 million was primarily due to the hiring of additional individuals to support the development of our product candidates, including an increase in stock-based compensation expense of $5.1 million.

- The increase in external discovery-related and other costs of $6.7 million was primarily due to the $2.6 million quarterly fee under the Adimab Collaboration Agreement, $1.4 million with respect to services performed and other fees under the Adimab Assignment Agreement and the Adimab Collaboration Agreement, $0.6 million related to services performed under the Research Collaboration and License Agreement with TSRI, and $2.1 million in other external costs, including professional and consulting services, insurance costs and software expenditures. We did not pay a quarterly fee to Adimab under the Adimab Collaboration Agreement during the six months ended June 30, 2021.

Acquired In-Process Research and Development Expenses

There was no IPR&D expense recognized during the six months ended June 30, 2022.

Acquired IPR&D expenses of $3.5 million for the six months ended June 30, 2021 consisted of the costs we incurred in the period under the Adimab Assignment Agreement for a $1.0 million milestone payment that became due to Adimab in February 2021 upon the dosing of the first patient in a Phase 1 clinical trial evaluating adintrevimab for the prevention of COVID-19 and a $2.5 million milestone payment that became due to Adimab in April 2021 upon the dosing of the first patient in the first Phase 2 clinical trial evaluating adintrevimab for the prevention of COVID-19. The amounts of these contingent payments were recognized as an IPR&D expense based on the nature of the associated assets acquired from Adimab on the date the milestone achievement became probable.

Selling, General and Administrative Expenses

(in thousands)	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021	Change
Personnel-related costs	$ 7,426	$ 5,549	$ 1,877
Professional and consultant fees	14,906	4,918	9,988
Other	992	228	764
Total selling, general and administrative expenses	$ 23,324	$ 10,695	$ 12,629

Selling, general and administrative expenses were $23.3 million for the six months ended June 30, 2022, compared to $10.7 million for the six months ended June 30, 2021. The $12.6 million increase in selling, general and administrative expenses was primarily due to the following:

- Personnel-related costs, including salaries, bonuses, benefits and other compensation-related costs were $5.6 million and stock-based compensation expense was $1.8 million for the six months ended June 30, 2022, compared to personnel-related costs of $3.0 million and stock-based compensation expense of $2.5 million for the six months ended June 30, 2021. The increase in personnel-related costs of $1.9 million was primarily due to the hiring of additional individuals to support our operations as we began operating as a public company, partially offset by the reversal of stock-based compensation expense related to the forfeiture of stock options in conjunction with the resignation of our former Chief Executive Officer and President.
- The increase in professional services and consultant fees of $10.0 million was primarily due to costs incurred as we began operating as a public company, including expenses related to corporate governance matters, director and officer insurance premiums, audit and other fees.
- Other costs remained relatively consistent between periods.

Other Income (Expense), Net

Other income (expense), net was $0.8 million and less than $0.1 million for the six months ended June 30, 2022 and 2021, respectively, consisting primarily of interest earned on invested cash balances.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in June 2020, we have not generated any revenue from any sources, including from product sales or government supply contracts, and have incurred significant operating losses and negative cash flows from operations. We expect to incur substantial expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates. To date, we have financed our operations with net proceeds of $464.7 million from sales of our preferred stock, and most recently, with net proceeds from our IPO in August 2021, in which we issued and sold 20,930,000 shares of our common stock, including 2,730,000 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. We received aggregate net proceeds from our IPO of $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

As of June 30, 2022, we had cash and cash equivalents of $474.9 million.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

(in thousands)	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Net cash used in operating activities	$ (116,441)	$ (57,311)
Net cash provided by investing activities	48,983	—
Net cash provided by financing activities	119	334,832
Net (decrease) increase in cash and cash equivalents	$ (67,339)	$ 277,521

Operating Activities

During the six months ended June 30, 2022, operating activities used $116.4 million of cash, primarily due to our net loss of $151.7 million, partially offset by non-cash charges of $8.8 million. Net cash provided by changes in our operating assets and liabilities consisted of a $8.4 million increase in accounts payable, partially offset by a $18.8 million decrease in prepaid expenses and other current assets, a $3.7 million decrease in accrued expenses, and a $3.0 million decrease in other non-current assets. The increase in accounts payable and decrease in accrued expenses was primarily due to the timing of vendor invoicing and payments. The decrease in prepaids expenses and other current assets and in other non-current assets was primarily due to our utilization of WuXi manufacturing deposits.

During the six months ended June 30, 2021, operating activities used $57.3 million of cash, primarily resulting from our net loss of $83.4 million, partially offset by non-cash charges of $4.0 million. Net cash provided by changes in our operating assets and liabilities for the six months ended June 30, 2021 consisted primarily of a $21.1 million increase in accrued expenses and a $2.2 million increase in accounts payable, both partially offset by a $1.1 million increase in prepaid expenses and other current assets. The increases in accounts payable and accrued expenses were primarily due to amounts owed to vendors in connection with our research and development activities, including increased external costs associated with clinical trials and manufacturing, as well as increases in accrued employee bonuses. The increase in prepaid expenses and other current assets was primarily due to prepayments for external research and development activities.

Investing Activities

Net cash provided by investing activities during the six months ended June 30, 2022 primarily consisted of $49.0 million in maturities of marketable securities.

We had no cash used in or provided by investing activities for the six months ended June 30, 2021.

Financing Activities

Net cash provided by financing activities during the six months ended June 30, 2022 primarily consisted of $0.1 million from exercises of stock options.

Net cash provided by financing activities during the six months ended June 30, 2021 primarily consisted of $335.3 million in net proceeds from the issuance of our Series C preferred stock in April 2021.

Funding Requirements

Our expenses could increase in connection with our ongoing activities, particularly as we advance the non-clinical and preclinical studies and the current and future clinical trials of our product candidates, including any associated manufacturing activities, and potential commercialization efforts. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including:

- the rate of progress in the development of adintrevimab and our other product candidates;
- the scope, progress, results and costs of discovery, non-clinical studies, preclinical development, laboratory testing and clinical trials for adintrevimab and future product candidates and associated development programs;
- the extent to which we develop, in-license or acquire other product candidates and technologies in our pipeline;
- the scope, progress, results and costs of manufacturing and validation activities associated with adintrevimab and with the development and manufacturing of our future product candidates and other programs as we advance them through preclinical and clinical development;
- the number and development requirements of product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;

- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- the timing and costs of securing sufficient capacity for clinical and commercial supply of our potential future product candidates, or the raw material components thereof;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval or EUA;
- the costs necessary to obtain regulatory approvals, if any, for products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the continuation of our existing licensing and collaboration arrangements and entry into new collaborations and licensing arrangements, if at all;
- the need and ability to hire additional research, clinical, development, scientific and manufacturing personnel;
- the costs we incur in maintaining business operations;
- the need to implement additional internal systems and infrastructure;
- the effect of competing technological, product and market developments;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs of operating as a public company; and
- the progression of the COVID-19 pandemic and emergence of potential outbreaks of other coronaviruses, including the impact of any business interruptions to our operations or to those of our contract manufacturers, suppliers or other vendors resulting from the COVID-19 pandemic or other similar public health crises.

As of August 15, 2022, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, government or private-party grants, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a common stockholder. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making acquisitions or capital expenditures or declaring dividends, which could adversely constrain our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through other sources, when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

During the three months ended June 30, 2022, there were material changes to our contractual obligations from those described in the 2021 Form 10-K. In April 2022, the total volume of contractually binding drug substance and drug product batches to be manufactured under the Commercial Manufacturing Agreement was reduced to $51.6 million, a decrease of $107.8 million from the previous commitment of minimum non-cancelable purchase obligations of $159.4 million. In addition, the Company received a credit in the low eight-figures to offset future services rendered by WuXi. In June 2022, we entered into a two year noncancelable agreement for dedicated laboratory and office space in Newton, Massachusetts. The monthly rental payments under the agreement include base rent charges of $0.7 million per year. For additional information, see Note 8 to our condensed consolidated financial statements appearing in this Quarterly Report on Form 10-Q.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. Our critical accounting policies and estimates are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in our 2021 Form 10-K. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations

could be materially affected. There have been no significant changes to our critical accounting policies and estimates from those described in the 2021 Form 10-K, except as disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations and cash flows is disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" 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 (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (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 officers, 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, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's 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 (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q 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.

We are not currently party to any material legal proceedings. From time to time, we may become involved in litigation or legal proceedings relating to claims arising from the ordinary course of business.

Item 1A. Risk Factors.

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since our inception, we have incurred significant losses, and we expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses were $51.0 million and $151.7 million, respectively, for the three and six months ended June 30, 2022 and $226.8 million for the year ended December 31, 2021. As of June 30, 2022, we had an accumulated deficit of $443.8 million. Since our inception, we have financed our operations with net proceeds of $464.7 million raised in our private placements of preferred stock, including the sale of our Series C preferred stock in April 2021, and approximately $327.5 million of net proceeds (after deducting underwriting discounts and offering expenses) from our IPO in August 2021. We have no products approved for commercialization and have never generated any revenue from product sales.

All of our product candidates are still in clinical and preclinical testing. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. Our expenses could increase substantially as we:

- continue to conduct our ongoing clinical trials of adintrevimab, as well as initiate and complete additional clinical trials of future product candidates or current product candidates in new indications or patient populations;
- continue to advance the preclinical development of our other product candidates and our preclinical and discovery programs, including any modification of adintrevimab and development and screening of additional antibodies;
- seek regulatory approval for any product candidates that successfully complete clinical trials;
- pursue marketing approvals or Emergency Use Authorization (“EUA”) and reimbursement for our product candidates;
- acquire or in-license other product candidates, intellectual property and/or technologies;
- validate our commercial-scale current good manufacturing practices (“cGMP”) manufacturing process;
- manufacture material under cGMP at our contracted manufacturing facilities for clinical trials and potential EUA, regulatory approval and commercial sales;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- comply with regulatory requirements established by the applicable regulatory authorities;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval or EUA;
- hire and retain additional personnel, including research, clinical, development, manufacturing quality control, quality assurance, regulatory and scientific personnel;
- add operational, financial, corporate development, management information systems and administrative personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

To date, we have not generated any revenue from product sales. To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, validating manufacturing processes, obtaining regulatory approval or EUA, and manufacturing, distributing, marketing, and selling any product candidates for

which we may obtain regulatory approval or EUA, as well as discovering and developing additional product candidates. All of our product candidates are in clinical or preclinical development. We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with product candidate development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform clinical trials or preclinical studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We commenced operations in June 2020, and our operations to date have been largely focused on organizing and staffing our company, business planning, raising capital, acquiring our technology and product candidates, and developing and manufacturing our clinical and preclinical product candidates, including undertaking preclinical studies, developing and validating our manufacturing process, and conducting clinical trials. To date, we have not yet demonstrated our ability to successfully complete pivotal clinical trials, obtain regulatory approvals or an EUA, or conduct sales and marketing activities necessary for successful commercialization, and we may not be successful in doing so. Additionally, if we submit a request for an EUA or submit an application for regulatory approval, for adintrevimab or any product candidate, we may not be successful in receiving such EUA or regulatory approval. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research and clinical focus to a company, if any of our product candidates are approved, capable of supporting commercial activities. We may not be successful in such a transition.

We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Our operations have consumed substantial amounts of cash since inception, and we expect to continue to incur significant expenses and operating losses over the next several years as we continue to develop our product candidate pipeline and build out our manufacturing capabilities for our product candidates, which, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that may not be commercially available for a number of years, if at all. If we obtain marketing approval or an EUA for any product candidate that we develop or otherwise acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of June 30, 2022, we had cash and cash equivalents of $474.9 million. As of August 15, 2022, we believe that our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2024. This estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We plan to use our cash and cash equivalents to fund clinical development, manufacturing supply and initial commercialization costs for adintrevimab, to fund clinical development and manufacturing supply costs of our next generation of antibody candidates to treat and prevent COVID-19, and for working capital and other general corporate purposes, including development of additional programs in our pipeline. Our existing cash and cash equivalents may not be sufficient to fund any of our product candidates through regulatory approval or EUA. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates and changes in regulation. The timing and amount of our funding requirements will depend on many factors, including:

- the rate of progress in the development of adintrevimab and our other product candidates;
- the scope, progress, results and costs of discovery, non-clinical studies, preclinical development, laboratory testing and clinical trials for adintrevimab and future product candidates and associated development programs;
- the extent to which we develop, in-license or acquire other product candidates and technologies in our pipeline;

- the scope, progress, results and costs of manufacturing and validation activities associated with adintrevimab and with the development and manufacturing of our future product candidates and other programs as we advance them through preclinical and clinical development;
- the number and development requirements of product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- the timing and costs of securing sufficient capacity for clinical and commercial supply of our potential future product candidates, or the raw material components thereof;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval or EUA;
- the costs necessary to obtain regulatory approvals, if any, for products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the continuation of our existing licensing and collaboration arrangements and entry into new collaborations and licensing arrangements, if at all;
- the need and ability to hire additional research, clinical, development, scientific and manufacturing personnel;
- the costs we incur in maintaining business operations;
- the need to implement additional internal systems and infrastructure;
- the effect of competing technological, product and market developments;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval or EUA;
- the costs of operating as a public company; and
- the progression of the COVID-19 pandemic and emergence of potential outbreaks of other coronaviruses, including the impact of any business interruptions to our operations or to those of our contract manufacturers, suppliers or other vendors resulting from the COVID-19 pandemic or other similar public health crises.

We will require additional capital to achieve our business objectives. Additional funds may not be available on a timely basis, on favorable terms or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, including higher inflation rates, changes in interest rates and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting, in part, from the ongoing COVID-19 pandemic. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

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

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, government or private-party grants, debt financings and license and collaboration agreements. We do not currently have any other committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future

commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to the Development of our Product Candidates

We may not be able to obtain an EUA from the FDA or comparable foreign regulators due to the emergence of variants, such as the Omicron BA.2 variant, which has shown reduced in vitro susceptibility to adintrevimab.

Based on feedback received from the FDA in the second quarter of 2022, we decided to pause our planned submission of an EUA request for adintrevimab as a result of the Omicron BA.2 sublineage becoming the predominant variant in the United States. Published data has shown that in *in vitro* assays, adintrevimab has markedly reduced neutralization activity against the Omicron BA.2, BA.4, and BA.5 sublineages. While we intend to continue to engage with the FDA and to monitor the evolution of SARS-CoV-2 and the *in vitro* activity of adintrevimab against predominant variants in the United States to determine the optimal timing for an EUA request, we cannot be certain that adintrevimab will neutralize future variants and that we will submit an EUA for adintrevimab or whether an EUA will be granted if we do submit such request.

All of our product candidates are currently in clinical and preclinical development. If we are unable to successfully develop, receive regulatory approval or EUA for and commercialize our product candidates for the indications we seek, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.

We currently have no products approved for commercial sale, and all of our product candidates are currently in clinical and preclinical development. In February 2021, we initiated a Phase 1 clinical trial evaluating adintrevimab. We have also advanced adintrevimab into global Phase 2/3 trials for the prevention and treatment of COVID-19 and reported preliminary safety and efficacy data (pre-Omicron) for both trials in March 2022. We have not previously conducted any later stage or pivotal clinical trials, have limited experience in preparing, submitting and prosecuting regulatory filings and have not previously submitted a biologics license application ("BLA") for any product candidate.

Our ability to generate revenue from our product candidates, which may not occur for several years, if ever, will depend heavily on the successful development, regulatory approval or granting of EUA for the prevention and/or treatment of COVID-19, obtaining of manufacturing supply, capacity and expertise and eventual commercialization of our product candidates. In the absence of a Public Health Emergency, we will not be able to receive an EUA. The success of adintrevimab or any other product candidates that we develop or otherwise may acquire will depend on several factors, including:

- the status of emerging variants where adintrevimab has limited to no activity against the virus, such as the Omicron BA.4 and BA.5 sublineages which are currently the predominant variants of SARS-CoV-2 in the United States;
- future SARS-CoV-2 VOCs could reduce the activity and effectiveness of adintrevimab as a potential prevention of or treatment for symptomatic COVID-19 and we may not be able to modify adintrevimab to improve binding on such variants and obtain sufficient data on the activity and effectiveness of re-engineered adintrevimab in order to support an EUA or regulatory approval and we may not be successful in identifying new antibodies that are suitable either as monotherapy or as combination therapy with adintrevimab to mitigate the risk of reduced activity against future SARS-CoV-2 variants;
- the continuing need for therapies for the prevention and treatment of COVID-19, including due to the continuation and severity of the pandemic, the development of SARS-CoV-2 into an endemic disease or the inability of other available therapies to address COVID-19;
- the timing and progress of discovery, preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- filing acceptable investigational new drug applications with the FDA, or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- the sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials, manufacture the product candidates and complete associated regulatory activities;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing and successfully develop, obtain regulatory approval or EUA for, and then successfully commercialize our product candidates;
- successful enrollment and timely completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- the costs associated with the discovery and development of any additional development programs and product candidates we identify in-house or acquire through collaborations;
- receipt of timely marketing approvals or EUAs from applicable regulatory authorities;

- developing and expanding sales, marketing and distribution capabilities and launching commercial sales of products, if approved or an EUA is obtained, whether alone or in collaboration with others;
- our ability to secure and maintain required state licenses for distribution of our products, if authorized or approved or an EUA is obtained, or other distribution disruptions;
- acceptance of the benefits and use of our products, including method of administration, if approved, by patients, the medical community and third-party payors, for their approved indications;
- the prevalence and severity of adverse events experienced with adintrevimab or any other product candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative therapies for any product candidate that we develop;
- the continued availability and sufficiency of government funding for the purchase and/or reimbursement of products for the diagnosis, prevention and treatment of COVID-19;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trademark and trade secret protection and regulatory exclusivity for our product candidates, if and when approved or an EUA is obtained, and otherwise protecting our rights in our intellectual property portfolio;
- our ability to maintain compliance with regulatory requirements, including Good Clinical Practices ("GCPs"), current Good Laboratory Practices, and cGMPs, and to comply effectively with other rules, regulations and procedures applicable to the development and sale of pharmaceutical products;
- potential significant and changing government regulation, regulatory guidance and requirements and evolving treatment guidelines;
- obtaining and maintaining third-party coverage and adequate reimbursement and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;
- our ability to maintain a continued acceptable safety, tolerability and efficacy profile of the products following approval or EUA; and
- the impact of any business interruptions to our operations or those of third parties with which we work, particularly in light of the current COVID-19 pandemic.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approval or EUA for any product candidate we develop, we may not be able to continue our operations.

Because adintrevimab and any future product candidates represent novel approaches to the prevention and treatment of disease, there are many uncertainties regarding the development, market acceptance, third-party reimbursement coverage and commercial potential of our product candidates.

COVID-19 is a relatively new disease and the prevention and treatment of this disease is evolving. Another party may be successful in producing a more efficacious prophylaxis or treatment for COVID-19, which may make it more difficult for us to obtain funding or lead to decreased demand for our potential products. Many small and large companies are developing therapies for the prevention and/or treatment of COVID-19, including antibodies, vaccines, antivirals, and other products. Some of these are being marketed and others are further along in the development and commercialization process than we are and several of these companies have access to larger pools of capital, including government funding, and broader infrastructure that may make them more successful at developing, manufacturing or commercializing their products globally for the prevention and/or treatment of COVID-19. The success or failure of other companies, or perceived success or failure, may impact our ability to obtain future funding or to successfully commercialize our products for COVID-19 prevention and/or treatment.

To date no monoclonal antibody has been approved for prevention (pre- or post-exposure) or treatment of COVID-19. The FDA has issued an EUA for tixagevimab co-packaged with cilgavimab for pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) and recently recommended a doubling of the dose due to the Omicron BA.1 and BA.1.1 variants. In addition, the FDA has issued EUAs for casirivimab/imdevimab and bamlanivimab/etesevimab for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for disease progression and who are not fully vaccinated or not expected to mount an immune response to vaccine and who have been exposed to an individual with SARS-CoV-2; however, due to lack of activity against the currently circulating Omicron variant, these antibodies are no longer authorized for use under an EUA. In addition, four monoclonal antibody products, casirivimab/imdevimab, bamlanivimab/etesevimab, sotrovimab, and bebtelovimab have received an EUA from the FDA for the treatment of COVID-19 in patients at high risk of disease progression and at this time only

bebtelovimab is authorized for use considering limited to no activity of other antibodies against the predominant variant (BA.5) in the U.S.

Because the use of engineered monoclonal antibodies is a relatively new and expanding area of novel therapeutic interventions, there are many uncertainties related to development, marketing, reimbursement and the commercial potential for our product candidates. There can be no assurance as to the length of the clinical trials, the number of patients the FDA or other comparable foreign regulatory authorities will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of antibody products or that the design of or data generated in these trials will be acceptable to the FDA or other comparable foreign regulatory authorities to support EUA, or similar authorization outside of the U.S., or marketing approval.

In addition, the FDA or other comparable foreign regulatory authorities may take longer than usual to come to a decision on any EUA, BLA or marketing authorization that we submit and may ultimately determine that there is insufficient data, information or experience with our product candidates to support an authorization or approval decision. The FDA or other comparable foreign regulatory authorities may also require that we conduct additional post-marketing studies or implement risk management programs, such as Risk Evaluation and Mitigation Strategies ("REMS"), until more experience with our product candidates is obtained. Finally, after increased usage, we may find that our product candidates do not have the intended effect or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory authorization or approval and commercial prospects.

The success of our business depends in part upon our ability to develop engineered monoclonal antibodies that can broadly neutralize SARS-CoV-2, SARS-CoV and additional pre-emergent coronaviruses. We may fail to deliver monoclonal antibodies that are effective in the prevention or treatment of symptomatic COVID-19. Even if we are able to identify and develop such antibodies, we cannot ensure that such product candidates will achieve authorization or marketing approval or EUA to safely and effectively prevent or treat symptomatic COVID-19 or other future coronavirus diseases.

If we uncover any previously unknown risks related to our antibodies, or if we experience unanticipated expenses, problems or delays in developing our product candidates, we may be unable to achieve our strategy of building a pipeline of monoclonal antibodies. Further, competitors who are developing products with similar technology may experience problems with their products that could identify problems that would potentially harm our business.

There is no assurance that the approaches offered by our product candidates will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for our proposed product candidates. Since our current product candidates and any future product candidates will represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend significant capital trying to obtain approval for product candidates that have an uncertain commercial market. The market for any products that we successfully develop will also depend on the cost of the product. If we do not successfully develop and commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our products, we will not become profitable, which would materially and adversely affect the value of our common stock.

In addition, our monoclonal antibodies may be provided to patients in combination with other agents provided by third parties or by us. The cost of such combination therapy may increase the overall cost of therapy, which may affect our ability to obtain reimbursement coverage for the combination therapy from governmental or private third-party medical insurers.

Newly emerging and future SARS-CoV-2 variants could reduce the activity and effectiveness of adintrevimab as a potential prevention of or treatment for symptomatic COVID-19.

Multiple variants of the virus that causes COVID-19 have been documented in the United States and globally during this pandemic. Although we have shown in pre-clinical studies that adintrevimab has the potential to broadly neutralize SARS-CoV-2 and the previously predominantly circulating variants, including Alpha, Beta, Delta, Delta Plus and Gamma, *in vitro* analyses to evaluate neutralizing activity of adintrevimab against the Omicron variant and its sublineages generated data showing reduced neutralizing activity of adintrevimab against the Omicron BA.1 and BA.1.1 sublineages compared to a reference strain and a lack of neutralizing activity against the Omicron BA.2, BA.4 and BA.5 sublineages. We have ongoing efforts to modify adintrevimab to improve binding to the Omicron variant and its sublineages, which are currently the predominant variants in the United States, in order to enhance neutralization potency against current and future novel variants, but such efforts may not be successful. Similarly, we may not be able to successfully modify adintrevimab, whether on a timely basis or at all, against newly emerging or future variants, in order to support an EUA or regulatory approval. Additionally, we may not be successful in identifying new antibodies that are suitable either as monotherapy or as combination therapy with adintrevimab to mitigate the risk of reduced activity against future SARS-CoV-2 variants.

New SARS-CoV-2 variants could be less susceptible to adintrevimab and its mechanism of action, or the results shown in pre-clinical studies may not be replicated in clinical studies. Further, we may not be able to address reductions in neutralization potency with adjustments to the adintrevimab dose or dosing frequency. This would significantly and adversely affect our ability to complete enrollment in our clinical trials, obtain authorization or approval of and to commercialize adintrevimab. In addition, if our planned dosing of 300 mg of adintrevimab were to be increased in response to reduction in neutralizing activity against dominant circulating SARS-CoV-2 variants or for other reasons, it could impact drug supply and pricing, which could adversely affect our commercial prospects.

Preclinical studies and clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates. If we are not able to obtain required regulatory approvals or EUAs, we will not be able to commercialize our product candidates, and our ability to generate product revenue will be adversely affected.

All of our product candidates are in clinical and preclinical development and their risk of failure is high. The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if our future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our product candidates for their targeted indications or support continued clinical development of such product candidates. Our current or future clinical trial results may not be successful.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA, the European Medicines Agency ("EMA"), or other foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA, EMA or other 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 preclinical studies or trials for our product candidates either prior to or post-approval, or they may object to elements of our clinical development program, requiring their alteration.

Of the large number of products in development, only a small percentage successfully complete the FDA's or comparable foreign regulatory authorities' approval processes and are commercialized. Even if we eventually complete clinical testing and receive approval of a new drug application, BLA or foreign marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

Furthermore, even if we obtain regulatory approval for our product candidates, we may still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from commercial and government payors, including government health administration authorities. If we are unable to successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

We may experience delays in beginning or conducting clinical trials or numerous unforeseen events before, during or as a result of clinical trials that could delay or prevent our ability to complete clinical trials, receive marketing approval or commercialize our product candidates.

We may experience delays in conducting any clinical trials, and we do not know whether our clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. For example, following our review of data generated in *in vitro* analyses demonstrating reduced neutralizing activity of adintrevimab against the Omicron SARS-CoV-2 BA.1 variant in both authentic and pseudovirus assays, in January 2022 we paused enrollment of new patients in both our EVADE and STAMP clinical trials to assess our dosing strategy in light of the spread of the Omicron BA.1 variant globally. Enrollment in EVADE and STAMP will not be resumed until the emergence of a variant susceptible to adintrevimab in regions where the trials are being conducted. We may experience numerous unforeseen events before, during or after the conduct of our clinical trials that could delay or prevent our ability to complete such trials or receive marketing approval for or commercialize our product candidates, or that could significantly increase the cost of such trials, including:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;

- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching agreement with the FDA, EMA or other regulatory authorities as to the design or implementation of our clinical trials;
- delays in obtaining regulatory authorization to commence a clinical trial;
- challenges in reaching an agreement on acceptable terms with clinical trial sites or prospective contract research organizations ("CROs"), the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- delays in obtaining institutional review board ("IRB") approval at each trial site;
- challenges in recruiting suitable patients to participate in a clinical trial;
- challenges in having patients complete a clinical trial or return for post-treatment follow-up;
- findings from inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with the applicable regulatory requirements, including the FDA's regulations and GCP requirements, or applicable regulatory requirements in other countries;
- addressing patient safety concerns that arise during the course of a trial, including the occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- inability to recruit and/or successfully contract with a sufficient number of clinical trial sites;
- difficulties in manufacturing sufficient quantities of product candidate for use in clinical trials;
- suspensions or terminations by IRBs at the institutions where such trials are being conducted, by the independent Data Monitoring Committee for such trial or by the FDA or other regulatory authorities due to a number of factors, including those described above;
- changes in regulatory requirements or guidance, or feedback from regulatory authorities that requires us to modify the design or conduct of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, especially if regulatory bodies require the completion of non-inferiority or superiority trials or the sample size needs to be increased based on the outcome rates observed during early trial conduct, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- enrollment in clinical trials may be impacted by the rate of infection prevalence in the relevant communities, which can change once a trial is initiated;
- the screen failure rate for clinical trials of our product candidates may be higher than we anticipate, requiring us to screen larger numbers of patients than originally planned;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks; for example, we conducted our STAMP treatment trial at sites outside of the United States; in the future, the applicable foreign regulatory authorities may determine that a placebo-controlled trial would expose patients to unacceptable health risks (because alternative effective therapies are or may become available in these regions during the conduct of the trial), which could delay enrollment of our trial and the authorization or approval of adintrevimab;
- the cost of clinical trials of our product candidates may be greater than we anticipate and we may not have funds to cover the costs;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may not be able to be procured or distributed as needed;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully and timely complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings or REMS;
- be subject to additional post-marketing testing requirements;
- be subject to changes in the way the product is administered; or
- have regulatory authorities withdraw or suspend their approval of the product or to impose restrictions on its distribution after obtaining marketing approval.

All of our product candidates will require extensive clinical testing before we are prepared to submit a BLA or marketing authorization application ("MAA"), for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for our product candidates and submit a BLA or MAA for regulatory approval of any of our product candidates or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, EMA or other regulatory authorities on our clinical development program, and the FDA, EMA or other regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

We cannot predict with any certainty whether or when we might complete a given clinical trial. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed or lost. In addition, any delays in our clinical trials could increase our costs, slow down the 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 and results of operations. 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.

The ongoing war between Russia and Ukraine may impact our ability to complete patient follow-up visits in our clinical trials.

The ongoing war between Russia and Ukraine may disrupt our ability to complete clinical trials in Ukraine. Certain data generated at these trial sites might not be able to be validated or study assessments may be missed, and our clinical trial sites in Ukraine may suspend or terminate trials and those patients could be forced to evacuate or choose to relocate, making them unavailable for further participation in clinical trials, adversely impacting the analysis of the patients enrolled in these trials and the overall safety and efficacy analysis of the trials. Furthermore, the ongoing war may prevent the FDA from auditing clinical trial sites in Ukraine. Interruptions of clinical trials may delay our clinical development and the potential authorization or approval of our product candidates, which could increase our costs and jeopardize our ability to commence product sales and generate revenues.

There can be no assurance that the Public Health Emergency will continue to be in place for an extended period of time and that the product we are developing for COVID-19 could be granted an EUA by the FDA or similar authorization by regulatory authorities outside of the United States if we decide to apply for such an authorization. If we do not apply for such an authorization or, if we do apply and no authorization is granted or, once granted, it is terminated, we will be unable to sell our product in the near future and instead, will be required to pursue solely the traditional regulatory approval processes of the FDA and comparable foreign authorities, which are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.

We may seek an EUA for the prevention and/or treatment of COVID-19 from the FDA or similar authorization from regulatory authorities outside of the United States, such as conditional marketing authorization from the EMA. If we apply for an EUA and it is granted, an EUA will authorize us to market and sell our COVID-19 monoclonal antibody under certain conditions of authorization as

long as the Public Health Emergency exists. The FDA expects that companies that receive an EUA for COVID-19 antibodies will proceed to licensure of their products under a full BLA. The FDA may issue an EUA during a public health emergency if the agency determines that the potential benefits of a product outweigh the potential risks and if other regulatory criteria are met.

There is no guarantee that we will apply for an EUA for adintrevimab or any of our product candidates, or other similar authorization or, if we do apply, that we will be able to obtain an EUA or such. If an EUA or other authorization is granted, we will rely on the FDA or other applicable regulatory authority policies and guidance governing products authorized in this manner in connection with the marketing and sale of our product. If these policies and guidance change unexpectedly and/or materially or if we misinterpret them, potential sales of our product could be adversely impacted. An EUA authorizing the marketing and sale of our product will terminate upon expiration of the public health emergency, which is a determination made by the Secretary of the Department of Health and Human Services ("HHS"). The FDA may also terminate an EUA if safety issues or other concerns about our product, such as loss of neutralizing activity against dominant circulating SARS-CoV-2 variants, arise or if we fail to comply with the conditions of authorization. We cannot predict how long the Public Health Emergency will remain in effect, the future dominant circulating SARS-CoV-2 variant(s), or the length of time a variant will circulate.

If we apply for an EUA or similar authorization from regulatory authorities outside of the United States, the failure to obtain such authorization or the termination of such an authorization, if obtained, would adversely impact our ability to market and sell our COVID-19 antibody, which could adversely impact our business, financial condition and results of operations. The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory authorization or approval for any product candidate, and it is possible that we may never obtain regulatory authorization or approval for any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any drug product candidates in the United States until we receive regulatory authorization with an EUA or approval of a BLA from the FDA, and we cannot market it in the European Union until we receive marketing authorization from the EMA, or other required regulatory approval in other countries. To date, we have had discussions with the FDA and Health Canada and have received scientific advice from the Medicines and Healthcare products Regulatory Agency, the Swedish Medical Products Agency, the Paul Ehrlich Institute, and the EMA regarding clinical development programs or regulatory approval for any product candidate within the United States, Canada, United Kingdom, Sweden, Germany and European Union, respectively. We have had no discussions with other comparable foreign authorities regarding clinical development programs or regulatory approval for any product candidate outside of these jurisdictions.

Prior to obtaining approval to commercialize any drug product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, EMA or other foreign regulatory agencies, that such product candidate is safe, pure and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

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 or with our interpretation of data from preclinical studies or 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 and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- we may be unable to collect sufficient data from clinical trials of our product candidates to support the submission and filing of a BLA with the FDA, MAA with the EMA or other submission;
- we may fail bioresearch monitoring, FDA inspection or comparable foreign regulatory authorities inspection;
- we may fail an FDA or comparable foreign regulatory authorities' inspection of our third-party contract manufacturing or testing facilities for which we contract and test clinical and commercial supplies;

- the FDA or comparable foreign regulatory authorities may find our contract manufacturing related activities (e.g., process validation, product characterization, product stability and expiry, and comparability establishment) insufficient for approval; and
- the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, the FDA, EMA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful, nor does it predict final results. For example, we may be unable to identify suitable animal disease models for our product candidates, which could delay or frustrate our ability to proceed into clinical trials or obtain marketing approval. Our product candidates may fail to show the desired safety and efficacy in clinical development despite having progressed through preclinical studies and initial clinical trials.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Interim, "top-line" and preliminary results from our clinical trials that we announce or publish from time to time may change as more 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 publish interim, top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary, top-line or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. 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 top-line 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.

Further, others, including regulatory agencies may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular development program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

Our preclinical studies and clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent, delay or limit the scope of regulatory approval of our product candidates, limit their commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

To obtain the requisite regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication. These trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any

time during the development process. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved.

We may fail to demonstrate with substantial evidence from adequate and well-controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and effective for their intended uses. In addition, the FDA or comparable foreign regulatory authorities may determine that antibody monotherapy products are not sufficient and that combination antibody therapies should become the standard of care. The current clinical data available from the STAMP and EVADE trials may be insufficient to support a BLA or marketing authorization and we may not be able to generate additional data if the FDA or comparable foreign regulatory authorities require additional trials in support of a BLA or marketing authorization.

If our product candidates are associated with undesirable effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may decide or be required to perform additional preclinical studies or to halt or delay further clinical development of our product candidates or to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial use for the product candidate, if approved. Some side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from monoclonal antibody therapy targeting an exogenous target, as with our adintrevimab product candidate, can be nonspecific.

If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug, the FDA, EMA or foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications, or require that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates that we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the product candidate. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates and may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or other requirements subject to a REMS;
- we may be required to change the way a product is administered or conduct additional trials;
- we could be sued and held liable for harm caused to patients;
- we may decide to remove the product from the market;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or foreign regulatory agency in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Lack of awareness or negative public opinion of monoclonal antibody therapies and increased regulatory scrutiny of monoclonal antibody therapies to prevent or treat COVID-19 may adversely impact the development or commercial success of our current and future product candidates.

The clinical and commercial success of our monoclonal antibody therapies will depend in part on public acceptance of the use of monoclonal antibody therapies to prevent of treat COVID-19. Any adverse public attitudes about the use of monoclonal antibody therapies may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and

their patients' willingness to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products once approved. Adverse events in our or others' clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates, all of which would have a negative impact on our business and operations.

We may experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, or we may pause, delay or terminate enrollment of our clinical trials, which could in turn delay or prevent our receipt of necessary regulatory approvals.

Successful and timely completion of clinical trials will require that we enroll, and maintain the enrollment of, a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors that may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates, or approved products for the conditions for which we are developing our product candidates.

Further, we may determine that enrollment in a clinical trial should be paused, delayed or terminated in order to revise trial protocols in light of preliminary data generated by the trial or new data generated in other studies. For example, following our review of data generated in external *in vitro* analyses examining the neutralizing activity of adintrevimab against the Omicron SARS-CoV-2 BA.1 variant in both authentic and pseudovirus assays, in January 2022 we paused enrollment of new patients in both our EVADE and STAMP clinical trials to assess dosing strategy and revise our trial protocols in light of the global spread of the Omicron variant and its sublineages. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or foreign regulatory authorities. We cannot predict how successful we will be at enrolling patients in future clinical trials. Patient enrollment is affected by other factors, including:

- the severity and difficulty of diagnosing the disease under investigation;
- the contraction of the public health crisis caused by COVID-19;
- the eligibility and exclusion criteria for the trial in question;
- the size of the patient population and process for identifying patients;
- the impact infection prevalence may have on enrollment;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the trial protocol, including but not limited to the use of a placebo control or active comparator;
- the perceived risks and benefits of the product candidate in the trial, including relating to monoclonal antibody and/or vaccine approaches;
- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation;
- the willingness of patients to be enrolled in our clinical trials;
- local, national and/or employer COVID-19 vaccine mandates;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, vaccine mandate policies, travel or quarantine policies that may be implemented, our ability to import and export clinical trial supplies, raw materials and commercial supply and other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll, or maintain the enrollment of, a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment pauses or delays in these clinical trials may

result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Breakthrough therapy designation by the FDA for any product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive marketing approval.

We may, in the future, apply for breakthrough therapy designation, or the equivalent thereof in foreign jurisdictions (where available), for our product candidates. A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

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

Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific indications. As such, we are currently focused on the development of adintrevimab for the prevention and treatment of symptomatic COVID-19, as well as advancing additional antibodies into clinical trials for the prevention and treatment of COVID-19 and other infectious diseases. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the 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 to such product candidate.

We plan to conduct and may in the future conduct additional clinical trials for our product candidates outside the United States, and the FDA and similar foreign regulatory authorities may not accept data from such trials conducted in locations outside of their jurisdiction.

We are currently conducting, and intend to conduct in the future, clinical trials outside the United States. The acceptance of trial data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions or may not be accepted at all. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole 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 U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence in accordance with GCP standards, and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, 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 sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar 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 or clearance for commercialization in the applicable jurisdiction.

We may not be successful in our efforts to build a pipeline of additional product candidates through internal efforts or through partnerships for discovery of novel antibody product candidates.

We may not be able to continue to identify and develop new product candidates in addition to our current pipeline. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, product candidates may be shown to have harmful side effects or other characteristics that indicate that they

are unlikely to be successfully developed, much less receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.

The evolving and constantly changing impact of COVID-19, which was declared a global pandemic by the World Health Organization ("WHO"), will directly affect the potential commercial prospects of our lead product candidate for the prevention and treatment of COVID-19. The severity of the global pandemic, the availability, administration and acceptance of vaccines, monoclonal antibodies, antiviral agents and other therapies, potential vaccine mandate policies, and the potential development of "herd immunity" by the global population will affect the design and enrollment of our clinical trials, the potential regulatory authorization or approval of our product candidates and the commercialization of our product candidates, if approved.

In addition, our business and operations may be more broadly adversely affected by the COVID-19 pandemic. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including public health directives and orders in the United States and the European Union that, among other things and for various periods of time, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events and ordered cessation of non-essential travel. Future remote work policies and similar government orders or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and may disrupt our ongoing research and development activities as well as our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Further, such orders also may impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities. Additionally, on September 9, 2021, President Biden issued an executive order obligating parties that contract with the federal government to require their employees to be fully vaccinated against COVID-19, with limited exceptions for certain accommodations, and on November 5, 2021 the Department of Labor's Occupational Safety and Health Administration ("OSHA") issued an emergency temporary standard (the "ETS") requiring all private employers with 100 or more workers to mandate COVID-19 vaccination or produce a weekly test for all employees. Although the executive order has been the subject of legal challenges and is currently enjoined nationwide, there can be no assurance that the executive order will not be upheld and enforced or that President Biden will not issue another executive order. Further, while the ETS was withdrawn effective January 26, 2022, OSHA has not withdrawn the ETS as a proposed rule. As a company that is likely to have 100 employees at the time such rule may become a final standard, we would be required to mandate COVID-19 vaccination of our workforce or require our unvaccinated employees to be tested weekly if the proposed rule becomes a final standard or if the executive order is upheld in the courts and we were to contract with the federal government. We or our suppliers may incur increased costs, labor disruptions or employee attrition as a result of these mandates. If we or other companies in our supply chain lose employees, it may be difficult in the current competitive labor market to find replacement employees, and this could have a material adverse effect on our business and results of operations.

To date, we have experienced some delays in our development activities as a result of the COVID-19 pandemic. In the future, we anticipate there could be additional or even significant disruptions, delays or uncertainties in our development activities as a result of the COVID-19 pandemic, including the ongoing shutdowns in China, as outbreaks occur and progress and some of our CROs, CDMOs and other service providers continue to be impacted. In December 2020, shipment of adintrevimab clinical supply by WuXi Biologics (Hong Kong) Limited ("WuXi") was delayed due to the introduction by the Chinese government of a new procedure for the approval of the export of products for the treatment of COVID-19. However, this type of delay is not anticipated to occur in the future, now that this export procedure has been implemented. In addition, we may experience related disruptions in the future that could severely impact our clinical trials, including:

- delays, difficulties or a suspension in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- interruption in clinical trial enrollment due to emergence of variant(s) against which adintrevimab is not anticipated to have activity;
- interruptions in our ability to manufacture and deliver drug supply for trials due to capacity constraints or lack of raw materials;
- interruptions to our ability to supply clinical trial material to clinical trial sites due to supply chain challenges;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- changes in local regulations (including potential vaccine mandates) as part of a response to the COVID-19 outbreak that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- uncertainty around patient enrollment rates due to unpredictable and variable regional rates of infection;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA and other regulatory authorities to accept data from clinical trials in these affected geographies.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global COVID-19 pandemic continues to rapidly evolve, particularly with regard to the rapid global spread of the Omicron variant and its sublineages. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence as of the date of this Quarterly Report, such as the ultimate geographic spread of the disease and the neutralizing activity of adintrevimab and any of our other potential COVID-19 product candidates against the dominant circulating variant(s) at any given time, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business, financial condition and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved.

The potentially addressable patient population for our current or future product candidates may be limited, if and when approved. Further, even if any of our product candidates are approved by the FDA or comparable foreign regulators, their approved indications may be limited to a subset of the indications that we targeted. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

We may develop adintrevimab and future product candidates for use in combination with other therapies or third-party product candidates, which exposes us to additional regulatory risks.

We may develop adintrevimab and future product candidates for use in combination with one or more currently authorized or approved therapies to prevent or treat COVID-19, or with therapies that may be authorized or approved in the future. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA, EMA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Combination antibody therapies appear to be favored by the FDA over monotherapy, and in the future the FDA, EMA and comparable foreign regulatory authorities may determine that monotherapy products should not be approved, eliminating our ability to commercialize adintrevimab as a monotherapy treatment.

We may also evaluate adintrevimab or any future product candidate in combination with one or more other third-party product candidates that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. If so, we will not be able to market and sell adintrevimab or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or comparable foreign regulatory authorities do not approve these other

product candidates, or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biologics or antivirals we choose to evaluate in combination with adintrevimab or any product candidate we develop, we may be unable to obtain approval of or market any such product candidate.

The United Kingdom's withdrawal from the European Union may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the European Union and require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed to by the United Kingdom and the European Union, as of January 1, 2021, the United Kingdom is no longer subject to the transition period (the "Transition Period") during which European Union rules continued to apply. A trade and cooperation agreement (the "Trade Cooperation Agreement") that outlines the post-Transition Period trading relationship between the United Kingdom and the European Union was agreed to in December 2020 and was formally entered into on May 1, 2021.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from European Union directives and regulations, Brexit has had, and will continue to have, a material impact on the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom. For example, Great Britain is no longer covered by the centralized procedures for obtaining European Union-wide marketing authorizations from the EMA, and a separate marketing authorization will be required to market our product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would delay or prevent us from commercializing our product candidates in the United Kingdom or the European Union and limit our ability to generate revenue and achieve and sustain profitability. While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the United Kingdom and the European Union, there are additional non-tariff costs to such trade that did not exist prior to the end of the Transition Period and frequent delays in the transit of goods between the United Kingdom and the European Union. Further, should the United Kingdom diverge from the European Union from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the European Union.

Risks Related to the Manufacturing of our Product Candidates

Monoclonal antibody therapies are complex and difficult to manufacture. We could experience manufacturing problems or may be unable to access raw materials due to global supply chain shortages, that result in delays in the development or commercialization of our product candidates or otherwise harm our business.

The manufacture of monoclonal antibody and other protein-based therapies are technically complex and necessitates substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical studies or commercialization efforts.

The manufacturers of pharmaceutical products must comply with strictly enforced cGMP requirements, state and federal regulations, as well as foreign requirements when applicable. Any failure of us or our contract manufacturing organizations to adhere to or document compliance to such regulatory requirements could lead to a delay or interruption in the availability of product for clinical trials or commercial use, or enforcement action from the FDA, EMA or other foreign or state regulatory authorities. If we or our manufacturers were to fail to comply with the FDA, EMA or other foreign or state regulatory authorities, it could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our potential future dependence upon others for the manufacture of our product candidates may also adversely affect our future profit margins, if any, and our ability to commercialize any product candidates that receive regulatory approval on a timely and competitive basis.

Biological products are inherently difficult and time-consuming to manufacture. Our program materials are manufactured and tested using technically complex processes and/or methods requiring specialized equipment and facilities and other production constraints, including a number of highly specific raw materials, cell lines and reagents with limited suppliers. Even though we aim to have backup supplies of raw materials, cell lines and reagents whenever possible, we cannot be certain they will be sufficient if our primary sources are unavailable. A shortage of a critical raw material, cell line or reagent, or a technical issue during development, manufacturing or testing, may lead to an inability to manufacture our product candidate, resulting in delays in clinical development or commercialization plans. Any changes in the manufacturing of components of the raw materials we use for manufacturing or testing of

our product candidates could result in unanticipated or unfavorable effects in our manufacturing processes or product quality or timelines, resulting in delays.

Any delay, failure or inability to manufacture or test on a timely basis can impact the timelines for our clinical trials or our commercialization plans. Such delay, failure or inability to manufacture or test can result from:

- a failure in the manufacturing process itself, for example by an error in manufacturing process, operator or human error, equipment failure, raw material or reagent failure, failure in any step of the manufacturing process, failure to maintain a cGMP environment or failure in quality systems applicable to manufacture (whether by us or our third-party contract development and manufacturing organization), sterility failures, testing failure or contamination during processing;
- a lack of reliability or reproducibility in the manufacturing process itself leading to variability in process execution or in product quality, which may lead to regulatory authorities placing a hold on a clinical trial or commercial supply and distribution or requesting further information on the process, which could in turn result in delays to the clinical trials or commercial supply and distributions;
- inability to obtain manufacturing or testing slots from contract development and manufacturing organizations (including contract testing laboratories that perform cGMP operations), or CDMOs, or to have enough manufacturing slots to manufacture our product candidates to meet clinical or commercial requirements and demands;
- unfavorable FDA, EMA or other foreign or state regulatory inspection of the manufacturing or testing site;
- inability to procure raw materials and reagents;
- loss, depletion or performance degradation of the cell line starting material; and
- loss of or close-down of any manufacturing facility used in the manufacture of our product candidates, or the inability to find alternative manufacturing capability in a timely fashion.

Our product candidates are biologics, and the manufacture of our product candidates is complex and subject to extensive regulations. If we or our contract manufacturers fail to comply with such regulations, regulatory authorities may impose sanctions or require remedial measures that could be costly or time-consuming, and our ability to provide supply of our product candidates for clinical trials or any approved products could be delayed or stopped.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers and testing facilities, labeling, packaging and storage facilities, and distributors, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured, tested, and stored in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and ensure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an EUA, BLA or MAA on a timely basis. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect us or any of our contract manufacturing, testing, and storage facilities involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted, and they could put a hold on one or more of our clinical trials (or could delay authorization of an EUA or approval of a BLA or MAA) if the facilities or quality systems of our or any of our CDMOs do not pass such audit or inspections. Certain of our CDMO's facilities have not yet been inspected by regulatory authorities. If any of our CDMO's facilities do not pass a pre-approval or other plant inspection, FDA or EMA approval (or authorization under EUA) of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, inspect or audit us or our CDMO's manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if compliance discrepancies with our product specifications or violations of applicable regulations occur independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business. If we or any of our CDMOs fail to maintain regulatory compliance, the FDA or EMA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be harmed. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified and approved through a BLA and/or MAA supplement, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully, if approved, or could delay commercial supply once approved. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure

one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials or commercial launch may be delayed or we could lose potential revenue.

We intend to rely on third parties to manufacture, test, label, package and store clinical and commercial supplies of our product candidates.

We are currently manufacturing, testing, labeling, packaging and storing our product candidates in partnership with CDMOs. We do not own or operate any facilities for product manufacturing, labeling, packaging, storage and distribution or testing. We are dependent on third parties to manufacture, label, package, store, and distribute the clinical and commercial supplies of our current and any future product candidates. We have established a relationship with WuXi to manufacture adintrevimab for supply under EUA (if authorized), BLA or MAA. Certain of our product candidates may have to compete with existing and future products, such as the annual influenza vaccine, that may have a lower price point. The actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates.

The facilities used by our contract manufacturers and contract testing labs to manufacture and test our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our EUA or BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel, including their ability to adequately separate products within their multi-product manufacturing facilities to prevent cross-contamination. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, 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 also intend to rely on third-party manufacturers to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. If we are not able to meet market demand for any approved product or if we are not able to produce supply at low enough costs, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business, financial condition, results of operations and prospects.

We engaged WuXi for development and generation of the production cell line starting material for adintrevimab manufacturing. The cell line expression technology used to generate the cell line is a licensed technology. Only high-level information identifying the general nature of the control elements in the expression vector has been provided to us. Details of the expression technology have not been provided, nor has there been sufficient information provided to enable a freedom-to-operate assessment of the expression technology.

In addition, we currently rely on WuXi's China-based facilities for adintrevimab clinical and commercial supply, and supply under EUA, if authorized. We will likely continue to rely on foreign CDMOs in the future. Foreign CDMOs may be subject to trade restrictions and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement of such material or delay or prevent the shipment of material out of the foreign country to the United States. Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our partnerships in China, which could have an adverse effect on our business, financial condition, results of operations and prospects.

Further, our reliance on third parties for manufacturing, testing, labeling, packaging and storing our product candidates entails risks to which we would not be subject if we manufactured, tested, labeled, packaged and stored our product candidates ourselves, including:

- inability to access sufficient manufacturing capacity;
- inability of our third-party manufacturers to execute our manufacturing procedures and other logistical support requirements appropriately;
- inability to negotiate additional manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- lack of ownership of the intellectual property rights in any improvements made by our third-party manufacturers in the manufacturing process for our product candidates; and
- disruptions to operations of our third-party manufacturers or suppliers by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

We cannot be sure that single-source suppliers for our manufacturing raw materials will remain in business, will not be subject to regulatory actions that impede our procurement of raw materials, or will not be purchased by one of our competitors or another company that is not interested in continuing to produce these raw materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, delays resulting in supply disruptions, diversion of resources or reduced manufacturing yields, any of which would adversely impact our business, financial condition and results of operations.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates, if authorized under EUA or approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure or total or partial suspension of production.

In July 2021, we entered into a license agreement with Biocon Biologics Limited ("Biocon") to combat COVID-19 in Southern Asia. Under the license agreement, we will provide Biocon materials and know-how to manufacture and commercialize an antibody treatment based on adintrevimab in India and select emerging markets. Biocon's ability to successfully manufacture in those territories may be restricted by foreign regulatory requirements.

We depend on sole-source third-party suppliers for materials that are necessary for the conduct of preclinical studies and manufacture and testing of our product candidates for clinical trials, and the loss of these third-party suppliers and manufacturers or their inability to supply us with sufficient quantities of adequate materials, or to do so at acceptable quality levels and on a timely basis, could harm our business.

Manufacturing and testing our product candidates require many specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture and testing of our product candidates. For example, we are reliant on WuXi as the procurer of the raw materials used in the manufacture of our product candidates, including certain single-source purification resins and cell culture media, which increases the risk of delays in production. In addition, to date, we have relied on WuXi as our only CDMO. The loss of this CDMO or its failure to supply us with material to support our commercial development program on a timely basis could impair our ability to develop our product candidates or otherwise delay the development process, which could adversely affect our business, financial condition and results of operations.

Some of our CDMO's raw material suppliers may not have the capacity to support clinical and commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers directly, and we or our CDMOs may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we or our CDMOs may experience delays in receiving key raw materials and equipment to support clinical or commercial manufacturing.

For some of these specialty materials, we and our CDMOs rely on and may in the future rely on sole-source vendors or a limited number of vendors. The supply of specialty materials and equipment that are necessary to produce our product candidates could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all. Switching suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, test, manufacture and market our product candidates in a timely and competitive manner, or at all. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

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

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure, armed conflict, or other natural or manmade accidents or incidents that result in the third parties upon whom we depend from being unable to fully utilize their facilities 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 the third parties upon whom we depend from using all or a significant portion of their manufacturing facilities, 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. Unforeseen natural or manmade accidents or incidents, such as freezer failure, natural disasters or theft, could also result in loss of cell line starting material. 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 the third parties on which we rely are unable to operate their facilities 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.

Any contamination or interruption in our manufacturing process, shortages of raw materials or failure of our suppliers of reagents to deliver necessary components could result in delays in our clinical development or commercialization schedules.

Given the nature of monoclonal antibody manufacturing, there is a risk of contamination, including in the manufacture of raw materials and in the manufacturing of our product candidates, or in the manufacturing or testing facility itself. Any contamination could adversely affect our ability to supply product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture or testing of our product candidates could adversely impact or disrupt the supply of commercial or clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our product candidates to perform differently or impact product stability and expiry and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes or could impact our planned development or commercialization schedule. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments, including oral options;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA, EMA or other foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning or REMS;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;

- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for adintrevimab and any other product candidates, once approved;
- the prevalence and severity of any side effects;
- any restrictions on the use of our products together with other medications or requirements that our products be used in combination with other products; and
- the ability to be effective against emerging variants as a monotherapy or combination therapy.

If we are unable to establish sales, marketing and distribution capabilities for adintrevimab or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We are currently establishing our commercial infrastructure to support the anticipated marketing and distribution of our product candidates, which we will need to achieve commercial success for adintrevimab or any other product candidate for which we may obtain marketing approval. There are risks involved with establishing our commercial infrastructure. For example, hiring a contract sales force or recruiting and training a sales force in the future is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we hire a contract sales force or recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating independent sales, marketing and market access organizations.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

The affected populations for adintrevimab or our other product candidates may be smaller than we or third parties currently project, which may affect our ability to enroll our clinical trials as well as the addressable markets for our product candidates.

Our projections of the number of people who are candidates to receive COVID-19 preventatives and treatments are estimates based on our knowledge and understanding of this disease. These estimates may prove to be incorrect and new studies may further reduce the estimated incidence or prevalence of this disease. The number of COVID-19 patients in the United States, the European Union and elsewhere may turn out to be lower than expected, and patients may not be otherwise amenable to treatment with our product candidates or may become increasingly difficult to identify and access, all of which would adversely affect our ability to enroll our clinical trials and our business, financial condition, results of operations and prospects. Further, even if we obtain approval for our product candidates, the FDA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of our product candidates.

A decline, or a widespread perception of a decline, in the spread or severity of the ongoing COVID-19 pandemic, including disease due to variants with relative or absolute resistance to other products, or an increase in available alternative therapies for or widespread immunity to COVID-19, could reduce the total addressable market for our lead product candidate for the prevention and treatment of COVID-19. Similarly, if new SARS-CoV-2 variants are less impacted by adintrevimab and its mechanism of action than expected and such variants become more prevalent in the ongoing pandemic, the number of patients that we will be able to successfully treat with adintrevimab, if approved, will be decreased.

The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors, including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access, and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on

information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated total addressable market range for the indications we are targeting has involved using a third party to model the future populations susceptible to and immune from SARS-CoV-2, based on assumptions such as vaccine adoption, efficacy, duration of effect, viral infectiousness and other factors we cannot control. Accordingly, these estimates included in this filing may turn out to be inaccurate. Further, the data and statistical information used in this Quarterly Report, and in our other filings with the SEC, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

Off-label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and/or subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product.

If our product candidates are approved by the FDA, we may only promote or market our product candidates for their specifically approved indications. We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice (the "DOJ"), the Office of Inspector General of HHS, state attorneys general, members of the U.S. Congress, and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries, investigations, and civil and criminal sanctions by the FDA, DOJ or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to correct information to healthcare practitioners, injunctions, or civil or criminal penalties.

Adintrevimab and our other monoclonal antibody product candidates may face significant competition from vaccines, antiviral agents and other therapeutics for COVID-19 that are currently available or in development.

Many biotechnology and pharmaceutical companies are developing therapeutics for COVID-19 or vaccines against SARS-CoV-2, the virus that causes COVID-19. Many of these companies, which include large pharmaceutical companies, have greater resources for development and established commercialization capabilities. For example, the FDA has approved or granted EUA for several vaccines and therapeutics for the prevention or treatment of COVID-19 developed or marketed by other companies, many of which are large, established biotechnology and pharmaceutical companies. Many of these companies have also been successful in securing government funding to support research and development and/or manufacturing of their product candidates as well as government contracts to purchase their supply orders. Additional vaccines and therapeutics are in development by other pharmaceutical and biopharmaceutical companies. Given the products currently approved or authorized for use as well as those in development by others, any therapies we may develop could face significant competition. If any other company develops therapeutics more rapidly or effectively than we do, develops a therapeutic that becomes the standard of care, develops a therapeutic at a lower cost or is more successful at commercializing an approved therapeutic, we may not be able to successfully commercialize adintrevimab for the prevention and treatment of symptomatic COVID-19, even if approved, or compete with other therapeutics or vaccines, which could adversely impact our business and operations.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery, development and manufacture of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors may also have significantly more experience commercializing drugs, particularly monoclonal antibodies and other biological products, that have been approved for marketing. Furthermore, a number of our competitors have received government contracts to support research and development of their product candidates and supply orders. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

We will face competition from other drugs or from other non-drug products currently approved or that will be approved in the future for the treatment of diseases we intend to target. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize drugs that are differentiated from products in the market;
- demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;

- obtain patent or other proprietary protection for our medicines;
- obtain required regulatory approvals;
- obtain placement in COVID-19 prevention and treatment guidelines from organizations such as the National Institutes of Health (the "NIH"), the Centers for Disease Control and Prevention (the "CDC"), WHO and the Infectious Diseases Society of America (the "IDSA"), and equivalent European guidelines;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate we develop. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects. In addition, the reimbursement structure of approved monoclonal antibodies by other companies could impact the anticipated reimbursement structure of our monoclonal antibodies, if approved, and our business, financial condition, results of operations and prospects.

Government entities, such as the CDC, NIH, the WHO and non-government professional societies, such as the IDSA and the European Society of Clinical Microbiology and Infectious Diseases (the "ESCMID") may produce treatment and/or prevention guidelines for COVID-19, including the use of monoclonal antibodies for these indications. If adintrevimab fails to be added to these guidelines, or if it receives poor positioning within those guidelines, payors and other customers may be less inclined to add adintrevimab to their formularies and/or prescribe adintrevimab, significantly reducing demand for adintrevimab, if approved.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving regulatory and marketing approval for, or commercializing, drugs before we do, which would have an adverse impact on our business and results of operations.

Adintrevimab may have to compete against products with Advance Purchase Agreements ("APAs") from the U.S. Federal Government.

In an EUA environment where the U.S. federal government signs an Advance Purchase Agreement with a manufacturer for a specific number of doses at a fixed price, product distribution is overseen by federal and state governments and product is ordered by institutions, prescribed by physicians and administered in a variety of settings. Product is free to the institutions and patients, but patients can be billed for administration costs. Currently, all oral antivirals and monoclonal antibodies are made available under APAs. Only Gilead's intravenous antiviral, remdesivir, which received full FDA approval for treatment of non-hospitalized patients (12 years of age or older) at high risk for COVID-19 disease progression in January 2022, is available under a standard purchase model where hospitals, clinics, and other institutions purchase product through distributors. In this environment, we may not qualify for a U.S. federal government contract. U.S. federal government contracts require contractors to meet a substantial number of qualifications, which we may not be able to meet, resulting in our inability to secure a federal contract. Additionally, our primary contract manufacturer is based in China, and the U.S. federal government may decide to avoid contracting with companies who have drug substance produced in China.

In an EUA environment where the U.S. federal government does not sign an APA, manufacturers follow a standard commercial model in which they sell product to wholesalers and/or distributors that ship the product to various sites of care. Under a standard commercial model, provider institutions and clinics can bill health plans for product. GlaxoSmithKline and Vir Biotechnology's sotrovimab was granted an EUA in May 2021 but did not receive an APA until November 2021; GlaxoSmithKline and Vir Biotechnology operated under a standard commercial model before receiving an APA.

If adintrevimab does not receive an APA but competes against products that do have an APA, adoption of adintrevimab could be limited because it would be competing against drugs that are paid for by the federal government and cost nothing to the purchasers or the patients.

Any product candidates for which we intend to seek approval as biologic products may face biosimilar competition sooner than anticipated.

If we are successful in achieving regulatory approval to commercialize any biologic product candidate that we develop, it may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biologic products subject to approval under the BLA pathway. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed by the FDA. 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 biological products.

There is a risk that any of our product candidates 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 our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. For example, in May 2021, the Biden administration expressed support for waiving intellectual property protections for COVID-19 vaccines amid concerns about vaccine access in foreign nations. Such waiver, if implemented, could extend to our product candidates. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our candidates, if approved, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences.

The success of our product candidates will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these therapies.

We believe our success depends on obtaining and maintaining coverage and adequate reimbursement for our product candidates, including adintrevimab for the prevention and treatment of COVID-19, and the extent to which patients will be willing to pay out-of-pocket for such products, in the absence of reimbursement for all or part of the cost. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government healthcare programs (e.g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations, and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement. The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians and other healthcare professionals may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided and reimbursement is adequate. In addition, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental nor investigational. Government entities, such as the CDC, the WHO and non-government professional societies, such as the IDSA and the ESCMID, may produce treatment and/or prevention guidelines for the prevention and treatment of COVID-19, including guidance regarding the use of monoclonal antibodies in these indications. If adintrevimab fails to be added to these guidelines, or if it receives poor positioning within these guidelines, payors and other customers may be less inclined to add adintrevimab to their formularies, significantly reducing demand for adintrevimab, if approved.

Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures

from third-party payors in connection with the potential sale of any of our product candidates. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system.

There can be no assurance that adintrevimab or any other product candidate, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that it will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our or our CDMO's, CROs', manufacturers' contractors', consultants' or collaborators' cybersecurity.

Maintaining the security of our computer information systems and communication systems is a critical issue for us and we devote considerable internal and external resources to network security and other security measures to protect our systems and users, but these security measures cannot provide absolute security. The multitude and complexity of our computer systems may make them susceptible to service interruption, breaches of security, disruption of data integrity, inadvertent errors that expose our data or systems, malicious intrusion, or random attacks.

Our internal computer systems, and those of third parties on which we rely, are also vulnerable to damage from, among other things, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, system malfunctions, cyberattacks or cyber-intrusions over the Internet, attachments to emails, phishing attacks, persons inside our organization, or persons with access to systems inside our organization. We have in the past and may in the future identify defects, errors, or vulnerabilities, which could inadvertently permit access to or exposure of customer data. The risk of a security incident, breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. For example, the ongoing conflict between Russia and Ukraine has led to an increase in cyberattacks on the Ukraine, including its government, companies, institutions and people, as well on the financial and communications infrastructure of other countries, companies and individuals therein. If any such event were to occur, it could lead to the loss, destruction, alteration, prevention of access to, disclosure, dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information and personal data) or data that is processed or maintained on our behalf, and cause interruptions in our operations, resulting in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly

increase our costs to recover or reproduce the data. Additionally, such events could lead to an interruption in our supply chain for the manufacturing of clinical and commercial drug substance and drug product, as well as related materials, and could significantly impact development and commercialization timelines and capabilities.

We cannot ensure that our data protection efforts and our investment in information technology, or the efforts or investments of CDMOs, CROs, consultants or other third parties with which we work, will prevent breakdowns or breaches in our or their systems or other cybersecurity incidents that cause loss, destruction, unavailability, alteration, dissemination of, or damage or unauthorized access to, our data, including personal data, assets and other data processed or maintained on our behalf, that could have a material adverse effect upon our reputation, business, operations or financial condition. We also rely on third parties to manufacture our product candidates, and any data breaches or other security events relating to their computer systems could also have a material adverse effect on our business. Controls employed by our information technology department and our CDMOs, CROs, consultants and other third parties could prove inadequate, and our ability to monitor such third parties' data security practices is limited. Due to applicable laws, rules, regulations and standards or contractual obligations, we may be held responsible for any information security failure or cyberattack attributed to our third-party service providers as they relate to the information we share with them.

Notifications and follow-up actions related to a data breach or other security incident could impact our reputation and cause us to incur significant costs, including significant legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident. However, we cannot guarantee that we will be able to detect or prevent any such incidents, or that we can remediate any such incidents in an effective or timely manner. Our efforts to improve security and protect data from compromise may also identify previously undiscovered instances of data breaches or other cybersecurity incidents. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information or personal data, we could incur material legal claims and liability and damage to our reputation, and the further development of our product candidates could be delayed. Any such event could also compel us to comply with federal and state breach notification laws, and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us to substantial liability under laws, rules, regulations and standards that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

The effects of a security breach or privacy violation could be further amplified during the current COVID-19 pandemic. In addition, the cost and operational consequences of implementing further data protection measures could be significant, and theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Further, we cannot be certain that our liability insurance will be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches, such coverage will cover any indemnification claims against us relating to any incident, will continue to be available to us on economically reasonable terms, or at all, or any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition and results of operations.

We are subject to a variety of privacy and data security laws, rules, regulations, policies, industry standards and contractual obligations, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

In Europe, the General Data Protection Regulation ("GDPR") took effect in May 2018. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of individuals within the European Economic Area ("EEA"), including clinical trial data. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data breaches to the competent national data processing authorities, requires having lawful bases on which personal data can be processed and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from the EEA to the United States and other jurisdictions that the European

Commission does not recognize as having "adequate" data protection laws; in July 2020, the Court of Justice of the European Union limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-U.S. Privacy Shield and imposing further restrictions on the use of standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our annual global turnover) and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

Relatedly, following the United Kingdom's withdrawal from the EEA and the European Union and the expiration of the Transition Period, companies must comply with both the GDPR and the legislation similar to the GDPR as incorporated into UK national law, which provides for significant fines of up to the greater of £17.5 million or 4% of global turnover and exposes companies to two parallel regimes with potentially divergent enforcement actions for certain violations. On January 1, 2021, the United Kingdom became a third country for purposes of the GDPR. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example with respect to how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. Pursuant to the EU-UK Trade and Cooperation Agreement of December 24, 2020, transfers of personal data from the European Union to the United Kingdom may continue to take place without a need for additional safeguards during a further transition period, which expires on the earlier of (i) the date on which an adequacy decision with respect to the United Kingdom is adopted by the European Commission; or (ii) the expiry of four months, which shall be extended by a further two months unless either the European Union or the United Kingdom objects. On June 28, 2021, the European Commission formally adopted its adequacy decision finding the United Kingdom to be adequate under the GDPR.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act (the "CCPA"), which took effect on January 1, 2020, became enforceable by the California Attorney General on July 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt out of certain sales of 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. Further, California voters approved a new privacy law, the California Privacy Rights Act (the "CPRA"), in the November 3, 2020 election, which will impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Although the CCPA currently exempts certain health-related information, including clinical trial data, the CCPA and the CPRA may increase our compliance costs and potential liability. Similar laws have been proposed in other states and at the federal level and, if passed, such laws may have potentially conflicting requirements that would make compliance challenging. For example, on March 2, 2021, Virginia enacted the Virginia Consumer Data Protection Act (the "CDPA"), which becomes effective on January 1, 2023, and on June 8, 2021, Colorado enacted the Colorado Privacy Act (the "CPA"), which takes effect on July 1, 2023. The CPA and CDPA are similar to the CCPA and CPRA but aspects of these state privacy statutes remain unclear, resulting in further legal uncertainty.

With the GDPR, CCPA, CPRA, CDPA, CPA and other laws, regulations and other obligations relating to privacy and data protection imposing new and relatively burdensome obligations, and with the substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. We are currently in the process of developing and updating our policies and procedures in accordance with requirements under applicable data privacy and protection laws and regulations. We do not currently have any formal data privacy policies and procedures in place and have not completed formal assessments of whether we are in compliance with all applicable data privacy laws and regulations. Additionally, if third parties with which we work, such as vendors or service providers, violate applicable laws, rules or regulations or our policies, such violations may also put our or our clinical trial and employee data, including personal data, at risk, which could in turn have an adverse effect on our business.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could seriously harm our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials

into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could seriously harm our business.

Risks Related to Our Dependence on Third Parties

We currently rely on third parties to conduct, supervise, analyze and monitor a significant portion of our research and preclinical testing and clinical trials for our product candidates, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We have engaged CROs and other third parties to conduct our planned preclinical studies or clinical trials, including our ongoing clinical trials of adintrevimab, and to monitor and manage data. We expect to continue to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. We also rely on third parties for their research and discovery capabilities. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs and other third parties conducting our trials may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO or clinical site or other vendor staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic.

In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

We rely on these parties for execution of our preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval for adintrevimab or any other product candidates.

We also expect to rely on other third parties to label, store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

We may seek collaborations with third parties for the discovery, development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators for the discovery, development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any such arrangements include regional and national pharmaceutical companies and biotechnology companies. If we enter into any additional such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. For example, our agreement with Biocon may not result in the successful development and commercialization of an antibody treatment for COVID-19 in India or other markets.

Collaborations involving our product candidates would 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 perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create 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 could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates 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;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future 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.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and enforce patent protection for our current and future product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technologies. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates. The risks associated with patent rights generally apply to patent rights that we in-license now or in the future, as well as patent rights that we may own now or in the future. We currently own two issued U.S. patents with claims directed to adintrevimab and ADG10, respectively, and one allowed U.S. patent application with claims directed to methods of use of adintrevimab, alone or in combination with ADG10 (an antibody-based product candidate previously considered for potential use in combination with adintrevimab for the treatment and prevention of COVID-19), which is projected to issue on August 16, 2022. In addition, although we own a number of pending patent applications, we may not be successful in prosecuting our filed patent applications to obtain issuance of additional patents. Accordingly, there can be no assurance that we will be able to obtain patent protection for our product candidates. Our pending Patent Cooperation Treaty ("PCT") patent applications, are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. Furthermore, our pending U.S. provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional U.S. patent application within one year of filing of the U.S. provisional patent application with the United States Patent and Trademark Office (the "USPTO"). If we do not timely file any national stage patent applications or non-provisional U.S. patent applications, we may lose our priority date with respect to our PCT and provisional U.S. patent applications, and any patent protection on the inventions disclosed in such patent applications. We can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. In addition, the coverage claimed in any such patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Failure to obtain and maintain such issued patents could have a material adverse effect on our ability to develop and commercialize our product candidates.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our resulting or granted patents will be sufficient to stop a competitor from developing and

commercializing a product, including a biosimilar product, that would be competitive with one or more of our product candidates. There is no assurance that all the potentially relevant prior art relating to our patent and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our future licensors were the first to file any patent application related to our product candidates and technologies. We additionally cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and, even if issued, may be challenged and invalidated or rendered unenforceable. Additionally, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO, challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Any successful challenge to any patents owned by or licensed to us after patent issuance could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could deprive us of rights necessary for the successful commercialization of any of our product candidates and technologies that we may develop. Even if they are unchallenged or such third-party challenges are unsuccessful, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates and technologies or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent and patent applications we hold, obtain or pursue with respect to our product candidates and technologies is challenged, or if they fail to provide meaningful exclusivity for our product candidates and technologies, it could threaten our ability to commercialize our product candidates and technologies. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection, if approved, would be reduced.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost, in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Any of the foregoing could have an adverse impact on our business and results of operations.

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

In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. We seek to protect our proprietary information, data and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. Although these agreements are designed to protect our proprietary information, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed with all third parties who may have helped to develop our intellectual property or who had access to our proprietary information, or that our agreements will not be breached. If any of the parties to these confidentiality agreements breaches or violates the terms of such agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result.

Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

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. Moreover, our competitors and other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors and other third parties could purchase our

products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or violate our intellectual property rights, design around our protected technology or develop their own 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 or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets and proprietary know-how were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets 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.

While we have confidence in these individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may 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.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first 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 product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic and other competing medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and 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. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, fail to exercise due diligence during the testing phase or regulatory review process, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension, or if the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, which could have a material adverse effect on our business.

We are a party to an assignment and license agreement with Adimab, pursuant to which we are obligated to make payments upon achievement of milestone events and royalties. If this agreement is terminated, our business and prospects will be materially and adversely affected.

We are party to an assignment and license agreement (the "Adimab Assignment Agreement") with Adimab, LLC ("Adimab"), which has assigned to us its rights to all existing coronavirus antibodies controlled by it and their derivatives, patents claiming such antibodies, know-how related to such antibodies, and biological and chemical materials specifically related to such antibodies. Pursuant to the Adimab Assignment Agreement, Adimab additionally granted us a non-exclusive, worldwide, sublicensable license under Adimab's antibody discovery and optimization platform technology to research, develop, make, use, and sell coronavirus antibodies and products containing or comprising coronavirus antibodies, provided that we may not use such licensed rights to discover or optimize antibodies. Under the Adimab Assignment Agreement, we are required to use commercially reasonable efforts to achieve specific development and regulatory milestones for products in certain major markets and to commercialize a product in any country in which we obtain marketing approval. This agreement additionally contains obligations that require us to make payments in the event certain milestone events are achieved and royalty payments on net sales of our products, if approved, on a product-by-product and country-by-country basis, for a period ending on the later of 12 years after the first commercial sale of such product in such country or the expiration of the last valid claim of any patent in such country that was assigned to us under the Adimab Assignment Agreement or that claims priority to any such patent. Our business is reliant upon the intellectual property rights assigned and licensed to us under the Adimab

Assignment Agreement. If we materially breach the Adimab Assignment Agreement, our license under the Adimab Assignment Agreement can be terminated, we can be required to return to Adimab the assigned patent rights and any patents or patent applications that claim priority to such patents, our rights to develop and commercialize our product candidates will be adversely affected, and we could be found liable for substantial monetary damages. If the Adimab Assignment Agreement is terminated as a result of our breach or otherwise, our business and prospects will be materially and adversely affected.

Our rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We rely on licensed intellectual property rights and intend to periodically explore a variety of additional possible strategic collaborations or licenses in an effort to gain access to additional product candidates, technologies or resources. At this time, we cannot predict what form such strategic collaborations or licenses might take in the future. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations and licenses can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations or licenses because of the numerous risks and uncertainties associated with establishing them. Any delays in entering into new strategic collaborations or licenses related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our current and future collaborations and licenses could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to comply with various development, diligence, commercialization and other obligations and meet development timelines, or exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses (for example, under the Adimab Assignment Agreement, we are required to use commercially reasonable efforts to achieve specified development and regulatory milestones for products in certain major markets and to commercialize a product in any country in which we obtain marketing approval);
- we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- we may not have the right to control the preparation, filing, prosecution and maintenance of patents and patent applications covering the technology that we license, and we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted and maintained in a manner consistent with the best interests of our business (for example, we have no rights to control the preparation, filing, prosecution or maintenance of the patents licensed to us under Adimab's antibody discovery and optimization platform technology under the Adimab Assignment Agreement);
- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenue from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Disputes may arise with respect to our current or future licensing agreements, including in connection with any of the forgoing, and, in spite of our efforts, our current and future licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate such license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements.

Our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such

litigation or for other reasons. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and licensed patents, and the enforcement or defense of our licensed patents or future owned patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, on September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act included a number of significant changes to United States patent law. These included provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Finally, the Leahy-Smith Act contained new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Further, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition 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 actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be involved in lawsuits to protect or enforce our future patents, the patents of our licensors or our other intellectual property or proprietary rights, which could be expensive, time consuming and unsuccessful and our future issued patents and the patents of our licensors covering our product candidates could be found invalid or unenforceable.

Competitors or other third parties may infringe, misappropriate or otherwise violate the patents of our licensors or any patents issued as a result of our pending or future patent applications. To counter infringement, misappropriation or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable or is not infringed, or may refuse to stop the other party in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our licensed or future owned patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our owned or licensed patent applications at risk of not yielding an issued patent.

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. 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. Third parties may also raise similar claims before administrative bodies in the United States

or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings, nullity proceedings or litigation or invalidation trials or invalidation proceedings). Such proceedings could result in revocation of or amendment to our future patents in such a way that they no longer cover our product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patent applications, should they issue as patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates.

Interference or derivation proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions or inventorship (and possibly also ownership) of inventions with respect to our patent applications or resulting patents, or patent applications or resulting patents of third parties. For example, we were notified in October 2020 that a third party claimed that one of its employees should be listed as an inventor on certain of our patent applications claiming SARS-COV-2 binding antibodies or their preparation; however, we believe such claim, if valid, would be limited to only a predecessor antibody to adintrevimab and, in any event, is without merit. The entity that assigned to us the relevant patent applications is required to indemnify us with respect to any potential financial ramifications relating to this claim. However, an unfavorable outcome in this claim or any other inventorship or ownership dispute could result in the loss of our exclusive rights in our technology and the associated intellectual property rights, require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Furthermore, any successful claim of inventorship by a third party could result in the loss of priority for our patent applications, potentially resulting in subsequently filed third-party patent applications having priority over our patent applications and thereby precluding our ability to obtain patent protection for the inventions claimed in our patent applications. 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, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. An adverse result in any litigation or defense proceedings could put one or more of our or our licensors' patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

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, 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. There could also 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 material adverse effect on the price of our common stock. Any of the foregoing could materially adversely affect our business, results of operations and financial condition.

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, WuXi has provided only high-level information to us identifying the general nature of the licensed control elements in the expression vector used in the production cell line starting material for adintrevimab manufacturing. Details of the expression technology have not been provided, nor has there been sufficient information provided to enable a freedom-to-operate assessment of the expression technology. We therefore cannot be sure that we have licensed all intellectual property rights that are relevant to or necessary for the commercialization of adintrevimab, and a third party may claim that our development or commercialization of adintrevimab infringes its intellectual property rights. We could be required to acquire or obtain a license to such intellectual property from such third parties, and we may be unable to do so on commercially reasonable terms or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may be required to redesign our manufacturing process for adintrevimab, which may not be feasible on a technical or commercial basis in a timely manner, and we may have to delay or abandon development of adintrevimab, which could have a material adverse effect on our business.

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. Our failure to identify and correctly interpret relevant third-party patents may negatively impact our ability to develop and market our products.

We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital 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. Even if we are able to in-license any such necessary intellectual property, it could be on a non-exclusive basis, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and we also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to redesign our product candidates, which may not be feasible on a technical or commercial basis, and we may have to delay or abandon development of the relevant program or product candidate, which could have a material adverse effect on our business.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain.

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, misappropriating or otherwise violating the patents, trademarks, and proprietary rights of third parties. As our current and future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. There is a substantial amount of litigation involving patents, trademarks, and other intellectual property rights in the biotechnology and pharmaceutical industries, including 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. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates and technologies. Third parties, including our competitors may initiate legal proceedings against us alleging that we are infringing, misappropriating or otherwise violating their patents, trademarks, or other intellectual property rights.

We cannot provide any assurance that our current and future product candidates do not infringe, misappropriate or otherwise violate other parties' patents, trademarks, or other proprietary rights, and competitors or other parties may assert that we infringe, misappropriate or otherwise violate their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and future product candidates, including oppositions, interference proceedings, reexaminations, post-grant review, *inter partes* review, or derivation proceedings before the USPTO in the United States or any equivalent regulatory authority in other countries. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize adintrevimab or any future product candidates. In order to successfully challenge the validity of any United States patents asserted against us in federal court, we would need to overcome a presumption of validity. As this burden is high and requires us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court of competent jurisdiction would agree with us and invalidate the claims of any such United States patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future.

While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that one of our product candidates infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. In addition, third parties may obtain patents in the future and claim that our product candidates or technologies infringe upon these patents. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe, misappropriate or otherwise violate a third party's valid intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. For example, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. 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 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. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease developing, manufacturing and commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed the patent at issue. We may also be required to indemnify collaborators or contractors against such claims. A finding of infringement, misappropriation or other violation of third-party intellectual property rights could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

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. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in-license needed technology. 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 litigation. There could also 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 an adverse effect on the price of our common shares. 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 be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our future 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 patent applications, our future patents issued as a result of our pending or future applications, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to enforce our rights or 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.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We rely on third parties to manufacture our product candidates, and we collaborate with additional third parties for the development of such product candidates. We therefore must, at times, share trade secrets with them. We may also conduct joint research

and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or our licensors have patent protection, but enforcement rights are not as strong as those in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Additionally, unforeseen global events such as the conflict between Russia and Ukraine, and sanctions relating to these events could affect our ability to file, prosecute, and defend patents and patent applications in those jurisdictions.

In addition, we or our licensors may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

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. If we 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.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, especially those relating to life sciences, which could make it difficult for us to stop the infringement, misappropriation or other violation of our future patents or marketing of competing products in violation of our proprietary rights generally. For example, Russia issued a decree in March of 2022 stating that patent owners who reside in a country "unfriendly" to Russia are not entitled to compensation in the event of patent infringement. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Moreover, our and our licensors' ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Proceedings to enforce our or our licensors' patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents or the patents of our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our licensors at risk of not issuing as patents, and could provoke third parties to assert claims against us. We and our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

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 enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license from third parties.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

For example, our license agreement with Biocon pursuant to which we will provide Biocon materials and know-how to manufacture and commercialize an antibody treatment based on adintrevimab in India and select emerging markets may also expose us to risks related to enforcement of our intellectual property rights.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. 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 patent and patent applications that we own, and we 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 of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. For example, as a result of the conflict between Russia and Ukraine, it is unclear whether payments to the Russian Patent Office and other entities will be allowed due to current and future sanctions, which have the potential to change daily. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish our product candidates, if approved for marketing, from the drugs of our competitors. We also expect to rely on trademarks to protect our company name. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. We currently have trademark applications pending in the United States and in certain foreign jurisdictions, but we have no issued trademark registrations in the United States. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. If we are found to infringe a third party's trademark rights, we could be forced to rebrand our company or our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively, and our competitive position, business, financial condition, results of operations and prospects may be significantly harmed. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Any of the foregoing events may have a material adverse effect on our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of any of our patents, should they issue;

- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor;
- we or our collaborators might not have been the first to make the inventions covered by our future issued patents or our pending patent applications;
- we or our collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our product candidates in all countries;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with customers, healthcare providers, including physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere 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, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the United States federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. In addition, the government may assert that a claim, including items or services resulting from a

violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates," that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that 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;
- HIPAA, which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent 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;
- the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to: (i) payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Even if we obtain regulatory approval for adintrevimab or any future product candidates, they will remain subject to ongoing regulatory oversight, which may result in significant additional expense.

Even if we obtain any regulatory approval for adintrevimab or any future product candidates, they will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submission of safety and other post-market information, among other things. Any regulatory approvals that we receive for adintrevimab or any future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-marketing testing and surveillance studies, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports.

Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval, commonly known as off-label promotion. The holder of an approved BLA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. A company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal and administrative penalties.

In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of adintrevimab or any future product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending marketing application or supplement to an approved application or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of products or product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize adintrevimab or any future product candidates and harm our business, financial condition, results of operations and prospects.

Even if we obtain authorization under an EUA or FDA or EMA approval any of our product candidates in the United States or European Union, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. In addition, in order to distribute adintrevimab, if authorized under an EUA, we will need to secure and maintain required state licenses.

Approval by the FDA in the United States or the EMA in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers and significantly impacts the United States pharmaceutical industry. The ACA, among other things contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. While the United States Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (the "Tax Act") included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, 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 eliminated the health insurer tax. The Bipartisan Budget Act of 2018 (the "BBA") among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On June 17, 2021, the U.S. Supreme Court dismissed on procedural grounds a challenge that argued that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed 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 or our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA and the Infrastructure Investment and Jobs Act, will remain in effect through 2031, unless additional congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single-source and innovator multiple-source drugs, beginning January 1, 2024. These laws may result in additional reductions in Medicare, Medicaid and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent 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 products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of this rule has been delayed until January 1, 2026. Further, in November 2020, CMS issued an interim final rule implementing the Most Favored Nation ("MFN") Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate

participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. As a result of litigation challenging the MFN Model, on December 27, 2021, CMS published a final rule that rescinded the MFN Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to the executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and 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 drug. 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 drugs. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for adintrevimab or any future product candidates. We cannot determine how changes in regulations, statutes, policies or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements or discontinuance of one or more of our products, if approved; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of adintrevimab or other product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition and results of operations.

Risks Related to Employee Matters and Managing Our Growth

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

We are highly dependent on the management, development, clinical, financial and business development expertise of our executive officers. Each of our executive officers may currently terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Certain of our directors, officers and key employees may have actual or potential conflicts of interest because of their positions with Adimab and/or other companies and may not be able to or may choose not to devote sufficient time and attention to our company, or may otherwise have conflicting incentives.

Terrance McGuire, a member of our board of directors, serves as a director of Adimab. Mr. McGuire is a beneficial owner of equity interests in Adimab. Mr. McGuire's position at Adimab and the ownership of any Adimab equity or equity awards creates, or may create the appearance of, conflicts of interest, including when this individual makes decisions that could have different implications for Adimab than for us. Other of our directors and executive officers also serve on the boards of directors of other private and public

companies. As a result, these individuals may not be able to devote their full time and attention to our company, which could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Since joining us, all of our executive officers have each spent a significant portion of their time devoted to us. While none of the executives has a minimum time commitment to us, each retains flexibility to ensure that he or she can re-allocate his or her time based on the needs of each business. These executives' time-allocation strategies may change over time based on the needs of each business or the executives' individual incentives to provide services to us relative to other businesses. On April 20, 2022, Laura Walker, Ph.D., our co-founder and Chief Scientific Officer, resigned as Senior Director of Antibody Sciences at Adimab. As a result, Dr. Walker is fully dedicated to leading Adagio's discovery and optimization efforts.

Adimab owns a significant percentage of our common stock, will be able to exert significant influence over matters subject to stockholder approval and may have interests that conflict with those of our other stockholders.

Adimab is currently our largest stockholder and beneficially owns approximately 24.3% of the voting power of our outstanding common stock according to a Schedule 13D filed by Adimab on June 24, 2022, which reported ownership as of June 22, 2022. As such, Adimab has the ability to substantially influence us through this ownership position. For example, Adimab, acting together with a small number of our other large stockholders, will be able to control elections of directors, amendments of our organizational documents or approval of any merger, amalgamation, sale of assets or other major corporate transaction. Any transferees or successors of all or a significant portion of Adimab's ownership in us will be able to exert a similar amount of influence over us through their ownership position.

Furthermore, certain of our directors, officers and key employees may have actual or potential conflicts of interest with us because of their positions or affiliations with Adimab or their beneficial ownership of equity in Adimab. Terrance McGuire, a member of the board of directors of Adimab, serves on our board of directors and retains his position and affiliation with Adimab. Our other stockholders may not have visibility into the Adimab ownership positions or other affiliations of any of our directors or officers with Adimab or its affiliates, which may change at any time through acquisition, disposition, dilution or otherwise. Any change in our directors' or officers' ownership in or positions with Adimab or its affiliates could impact the interests of those holders. Adimab's interests may not always coincide with our corporate interests or the interests of our other stockholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other stockholders. So long as it continues to own a significant portion of our outstanding voting securities, Adimab will continue to have considerable influence in all matters that are subject to approval by our stockholders and will be able to strongly influence our other decisions.

We may expand our clinical development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

Depending on our development progresses, we may experience growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product development, regulatory affairs, manufacturing and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our potential future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and 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. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, 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, 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 significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government

healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

An active trading market for our common stock may not continue to be developed or sustained.

Prior to the IPO, there was no public market for our common stock. Although our common stock is listed on the Nasdaq Global Market, if an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares at an attractive price or at all.

The trading price of the shares of our common stock has been and may continue to be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. Since the IPO and through August 8, 2022, our common stock has traded at prices ranging from $2.41 to $78.82 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the timing, progress and results of our ongoing clinical trials of adintrevimab or the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for adintrevimab or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of adintrevimab or any other product candidate;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- announcements by our competitors of new product candidates or technologies, or the results of clinical trials or regulatory decisions;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- our relationships with our collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions; and

- other events or factors, many of which are beyond our control.

The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations, including as a result of the ongoing COVID-19 pandemic, the ongoing conflict between Russia and Ukraine, increases in inflation rates and disruptions to global supply chain, that have often been unrelated or disproportionate to the prospects of the issuer and which have resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

We previously identified a material weakness in our internal control over financial reporting. We may identify future material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we fail to establish and maintain adequate internal control over financial reporting, we may not be able to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective, which may adversely affect our business.

We previously identified a material weakness in our internal control over financial reporting that was identified during the preparation of our March 31, 2021 financial statements. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim condensed consolidated financial statements will not be prevented or detected on a timely basis.

Although we have determined that the previously identified material weakness has been remediated as of December 31, 2021, we cannot assure you that we will not identify other material weaknesses in the future, which could negatively impact our results of operations in future periods.

Ensuring that we have adequate internal control over financial reporting in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with the IPO, we began the process of documenting, reviewing and improving our internal control over financial reporting for compliance with the rules and regulations of the Securities and Exchange Commission (the "SEC"), which requires annual management assessment of the effectiveness of our internal control over financial reporting.

Implementing any appropriate changes to our internal control over financial reporting may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in establishing and maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business.

Further, if we are unable to meet the demands that have been placed upon us as a public company, including the rules and regulations of the SEC, we may be unable to accurately report our financial results in future periods, or report them within the timeframes required by law or stock exchange regulations. Failure to comply with the rules and regulations of the SEC, when and as applicable, could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. Any failure to maintain or implement required effective internal control over financial reporting, or any difficulties we encounter in their implementation, could result in additional material weaknesses, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Furthermore, if we cannot provide reliable financial reports or prevent material misstatements due to fraud or error, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information. We also could become subject to investigations by The Nasdaq Stock Market ("Nasdaq"), the SEC or other regulatory authorities, which could require additional financial and management resources.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about 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 equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our

company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

A significant portion of our total outstanding shares are available for immediate resale. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended (the "Securities Act"), registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options and the restrictions of Rule 144 in the case of our affiliates.

Additionally, the holders of an aggregate of approximately 44.0 million shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors will have the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents will also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- stockholders will not be entitled to remove directors other than by a $66^{2}/_{3}$% vote and only for cause;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and current beneficial owners of five percent or more of our common stock and their respective affiliates beneficially own a majority of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of the IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in the previous three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure.
- an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation;
- exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, 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. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a "smaller reporting company" as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We are therefore entitled to rely on certain reduced disclosure requirements for as long as we remain a smaller reporting company, such as an exemption from providing selected financial data and certain executive compensation information. In addition, for as long as we are a smaller reporting company with less than $100 million in annual revenue, we would be exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act.

These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile.

We have broad discretion in the use of our cash and cash equivalents, including the net proceeds from our initial public offering.

We have broad discretion over the use of our cash and cash equivalents, including the net proceeds from the IPO. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply our cash and cash equivalents effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of our cash and cash equivalents. You will not have the opportunity to influence our decisions on how to use our cash and cash equivalents.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and 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 the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is 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. 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. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations and prospects.

These exclusive forum provisions may result in increased costs for investors to bring a claim. Further, these exclusive forum provisions 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 lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

We have incurred and will continue to incur increased costs and demands upon management as a result of becoming a public company, which could lower our profits or make it more difficult to run our business.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act, and related rules implemented by the SEC and Nasdaq. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees, or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation.

In particular, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), in our second annual report on Form 10-K due to be filed with the SEC after becoming a public company, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not 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 engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. As of December 31, 2021, we had U.S. federal net operating loss ("NOL") carryforwards of $221.9 million, which may be available to reduce future taxable income and have an indefinite carryforward period but are limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2021, we had state NOL carryforwards of $81.9 million, which may be available to reduce future taxable income, of which $3.4 million have an indefinite carryforward period while the remaining $78.5 million begin to expire in 2041. As of December 31, 2021, we also had U.S. federal and state research and development tax credit carryforwards of $3.3 million and $1.3 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2041 and 2036, respectively.

Under the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), federal NOLs incurred in taxable years beginning after December 31, 2017 and in future taxable years may carry forward indefinitely, but the deductibility of such federal NOLs incurred in taxable years beginning after December 31, 2020 may be limited. It is uncertain how various states will respond to the Tax Act and the CARES Act. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. The IPO, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced, and may in the future experience, ownership changes as a result of shifts in our stock ownership, some of which may be outside of our control. If an ownership change has occurred or occurs in the future, and our ability to use our NOL carryforwards is materially limited, it would harm our financial condition and results of operations by effectively increasing our future tax obligations.

We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. Beginning in 2022, the Tax Act eliminates the currently available option to deduct research and development expenditures and requires taxpayers to amortize them over five years. The U.S. Congress is considering legislation that would defer the amortization requirement to future periods; however, there is no assurance that the provision will be repealed or otherwise modified. If the requirement is not repealed or modified, it will have a material impact on our cash flows beginning in 2022.

Our business activities will be subject to the Foreign Corrupt Practices Act (the "FCPA") and similar anti-bribery and anti-corruption laws.

As we expand our business activities outside of the United States, including our clinical trial efforts, we will be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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, prevent new products and services from being developed or commercialized in a timely manner 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, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the 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 or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently from December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, 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.

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 and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Since then, the FDA has resumed both domestic and foreign inspections subject to travel restrictions. The FDA continues to adapt to the evolving COVID-19 pandemic, and has increasingly relied on alternative inspectional tools, including product sampling, records requests under Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act, and remote regulatory assessments, in lieu of or to supplement traditional in-person inspections. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting business as usual or conducting 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.

Unfavorable global economic conditions and geopolitical events could adversely affect our business, financial condition or results of operations, including clinical trials.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact our clinical trials, the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Some of our clinical trial sites are in regions impacted by the ongoing geopolitical conflict between Russia and Ukraine. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from the current COVID-19 pandemic, higher inflation and interest rates, political disruption or other geopolitical events, including an expansion of the conflict between Russia and Ukraine or instigation of other military conflicts, could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

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

Use of Proceeds

On August 5, 2021, our Registration Statement on Form S-1, as amended (File No. 333-257975), was declared effective in connection with the IPO, pursuant to which we sold an aggregate of 20,930,000 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $17.00 per share. Morgan Stanley & Co. LLC, Jefferies LLC, Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC acted as joint book-running managers.

The IPO closed on August 10, 2021. The aggregate net proceeds received by the Company from the IPO were approximately $327.5 million, after deducting underwriting discounts and commissions of $24.9 million and offering expenses payable by the Company of $3.4 million. In connection with the IPO, no payments were made by us to directors, officers or persons owning ten percent or more

of our common stock or to their associates or to our affiliates. There has been no material change in the planned use of proceeds from the IPO as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on August 6, 2021.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Period	(a) Total Number of Shares (or Units) Purchased		(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
April 1, 2022 to April 30, 2022	—		—	—	—
May 1, 2022 to May 31, 2022	—		—	—	—
June 1, 2022 to June 30, 2022	992,648	[1]	$ 0.002	—	—
Total	992,648		$ 0.002	—	—

[1] We repurchased shares of our common stock that were previously issued upon the early exercise of employee stock options in connection with the exercise of our repurchase right upon cessation of employment of certain of our employees and directors.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on August 10, 2021).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on August 10, 2021).
10.1+	Employment Agreement by and between the Registrant and David Hering, dated July 5, 2022 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on July 5, 2022).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1^	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2^	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

\+ Indicates management contract or compensatory plan.

^ Furnished herewith and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

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

Adagio Therapeutics, Inc.

Date: August 15, 2022

By: /s/ David Hering, M.B.A.

David Hering, M.B.A.
Chief Executive Officer
(Principal Executive Officer)

Date: August 15, 2022

By: /s/ Jane Pritchett Henderson

Jane Pritchett Henderson
Chief Financial Officer and
Chief Business Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Hering, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Adagio Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 15, 2022

By: /s/ David Hering, M.B.A.

David Hering, M.B.A.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jane Pritchett Henderson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Adagio Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 15, 2022

By: /s/ Jane Pritchett Henderson

Jane Pritchett Henderson
Chief Financial Officer and
Chief Business Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Adagio Therapeutics (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 15, 2022

By: /s/ David Hering, M.B.A

David Hering, M.B.A
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Adagio Therapeutics (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 15, 2022

By: /s/ Jane Pritchett Henderson

Jane Pritchett Henderson
Chief Financial Officer and
Chief Business Officer
(Principal Financial Officer)