UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

or

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

For the transition period from _____ to _____

Commission File Number: 001-40407

Vera Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**81-2744449**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
8000 Marina Boulevard, Suite 120 Brisbane, California	
(Address of principal executive offices)	**94005 (Zip Code)**

Registrant's telephone number, including area code: (650) 770-0077

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Class A common stock, $0.001 par value per share	**VERA**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§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 May 12, 2022, the registrant had 27,065,473 shares of common stock, $0.001 par value per share, outstanding, consisting of 26,769,188 shares of Class A common stock, $0.001 par value per share and 309,238 shares of Class B common stock, $0.001 par value per share.

Table of Contents

In this Quarterly Report on Form 10-Q, unless otherwise stated or as the context otherwise requires, references to "Vera," "the Company," "we," "us," "our" and similar references refer to Vera Therapeutics, Inc.

This Quarterly Report on Form 10-Q also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

An investment in shares of our Class A common stock involves a high degree of risk. Below is a list of some of the material risks associated with our business. This summary does not address all of the risks that we face. Additional discussion of the risks listed in this summary, as well as other risks that we face, are set forth under Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q:

- We have not completed any clinical trials for our lead product candidate, atacicept, and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs of our product candidates or future commercialization efforts.

- We have incurred net losses since inception, and we expect to continue to incur net losses for the foreseeable future. In addition, we may be unable to continue as a going concern over the long-term.
- We are substantially dependent on the success of our product candidates, atacicept and MAU868, which are currently in the clinical development stage. If we are unable to complete development of, obtain regulatory approval for and commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with immunoglobulin A nephropathy (IgAN), the availability of competitive products, and significant competition for recruiting patients in clinical trials.
- The incidence and prevalence for target patient populations of atacicept in specific indications are based on estimates and third-party sources. If the market opportunities for atacicept, or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.
- Interim, initial, “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than us.
- Changes in methods of manufacturing or formulation of our product candidates may result in additional costs or delays.
- Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.
- Even if any product candidate we develop receives regulatory approval, it could be subject to significant post-marketing regulatory requirements and will be subject to continued regulatory oversight.
- Biosimilars to our product candidates may provide competition sooner than anticipated.
- The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our clinical trials.
- Unfavorable global economic conditions could adversely affect our business, financial condition and results of operations.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies. If we or our potential licensors, licensees, or collaborators are unable to obtain or maintain patent protection with respect to our product candidates, proprietary technologies and their uses, our business, financial condition, results of operations and prospects could be significantly harmed.
- The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees and key consultants.
- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.
- If we breach our license agreement (Ares Agreement) with Ares Trading S.A. (Ares), an affiliate of Merck KGaA, Darmstadt, Germany, related to atacicept, or the license agreement with Novartis International Pharmaceutical AG (Novartis) related to MAU868, we could lose the ability to continue the development and commercialization of atacicept or MAU868, respectively.
- If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.
- Patent terms may be inadequate to protect our competitive position on atacicept, MAU868 or any future product candidates we may develop for an adequate amount of time.

- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize atacicept, MAU868 or future product candidates we may develop and our business, financial condition, results of operations and prospects could be significantly harmed.
- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our product for patients, if approved, could be delayed or prevented.
- If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.
- The price of our Class A common stock may be volatile, and you could lose all or part of your investment.
- If we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Class A common stock.
- Our principal stockholders and management own a significant percentage of our outstanding voting stock and will be able to exert significant control over matters subject to stockholder approval.
- Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.
- We may be subject to securities litigation, which is expensive and could divert management attention.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

VERA THERAPEUTICS, INC.
Condensed Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 111,506	$ 79,674
Marketable securities	39,432	—
Prepaid expenses and other current assets	6,805	2,863
Total current assets	157,743	82,537
Restricted cash, noncurrent	293	293
Property and equipment, net	16	—
Operating lease right-of-use assets	6,275	—
Prepaid expenses and other noncurrent assets	67	51
Non-marketable equity securities	580	867
Total assets	$ 164,974	$ 83,748
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,328	$ 1,385
Operating lease liabilities	2,490	—
Restructuring liability	—	377
Accrued expenses and other current liabilities	10,151	5,928
Total current liabilities	19,969	7,690
Long-term debt	4,937	4,923
Operating lease liabilities, noncurrent	5,357	—
Restructuring liability, noncurrent	—	1,257
Accrued and other noncurrent liabilities	286	286
Total liabilities	30,549	14,156
Stockholders' equity		
Preferred stock, $0.001 par value; 10,000,000 authorized as of March 31, 2022 and December 31, 2021; no shares issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Class A common stock, $0.001 par value; 500,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 26,756,235 and 20,968,376 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	27	21
Class B non-voting common stock, $0.001 par value; 14,600,000 shares authorized as of March 31, 2022 and December 31, 2021; 309,238 shares issued and outstanding as of March 31, 2022 and December 31, 2021.	—	—
Additional paid-in capital	275,551	193,627
Accumulated other comprehensive loss	(12)	—
Accumulated deficit	(141,141)	(124,056)
Total stockholders' equity	134,425	69,592
Total liabilities and stockholders' equity	$ 164,974	$ 83,748

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

VERA THERAPEUTICS, INC.
Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 12,549	$ 2,932
General and administrative	4,472	1,784
Total operating expenses	17,021	4,716
Loss from operations	(17,021)	(4,716)
Other income (expense):		
Interest income	26	2
Interest expense	(118)	—
Other income	315	—
Change in fair value of non-marketable equity securities	(287)	—
Total other (expense) income	(64)	2
Net loss	$ (17,085)	$ (4,714)
Other comprehensive loss:		
Change in unrealized loss on marketable securities	(12)	—
Total loss and other comprehensive loss	$ (17,097)	$ (4,714)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.71)	$ (12.23)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	24,227,282	385,401

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

VERA THERAPEUTICS, INC.
Condensed Statements of Stockholders' Equity
For the Three Months Ended March 31, 2022 and 2021
(unaudited)
(in thousands, except share amounts)

	Class A Common Stock		Class B Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity
Balance as of December 31, 2021	**20,968,376**	**$ 21**	**309,238**	**$ —**	**$ 193,627**	**$ —**	**$ (124,056)**	**$ 69,592**
Issuance of common stock from underwritten follow-on offering, net of offering costs	5,742,026	6	—	—	80,028	—	—	80,034
Issuance of common stock pursuant to exercise of options	17,946	—	—	—	65	—	—	65
Issuance of common stock pursuant to employee stock purchase plan	8,458	—	—	—	169	—	—	169
Issuance of common stock upon vesting of restricted stock units	19,429	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	1,662		—	1,662
Unrealized loss on marketable securities						(12)		(12)
Net loss	—	—	—	—	—	—	(17,085)	(17,085)
Balances as of March 31, 2022	**26,756,235**	**$ 27**	**309,238**	**$ —**	**$ 275,551**	**$ (12)**	**$ (141,141)**	**$ 134,425**

	Redeemable Convertible Preferred Stock		Class A Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance as of December 31, 2020	182,772,372	$ 139,576	355,296	$ —	$ 2,099	$ (91,447)	$ (89,348)
Issuance of Class A common stock upon exercise of options	—	—	113,683	—	342	—	342
Stock-based compensation	—	—	—	—	404	—	404
Net loss	—	—	—	—	—	(4,714)	(4,714)
Balances as of March 31, 2021	**182,772,372**	**$ 139,576**	**468,979**	**$ —**	**$ 2,845**	**$ (96,161)**	**$ (93,316)**

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

VERA THERAPEUTICS, INC.
Condensed Statements of Cash Flows
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (17,085)	$ (4,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and accretion	9	35
Reduction in the carrying amount of operating lease right-of-use assets	564	—
Stock-based compensation	1,662	404
Restructuring payments	—	(590)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,942)	(127)
Other assets	271	—
Accounts payable	5,943	(198)
Accrued and other current liabilities	4,223	1,069
Operating lease liabilities	(626)	—
Net cash used in operating activities	(8,981)	(4,121)
Cash flows from investing activities		
Purchase of property and equipment	(18)	—
Purchase of marketable securities	(39,437)	—
Net cash used in investing activities	(39,455)	—
Cash flows from financing activities		
Proceeds from exercise of stock options and employee stock purchase plan	234	342
Proceeds from issuance of Class A common stock offering, net of underwriting discounts and commissions	86,130	—
Payment of costs related to underwritten follow-on offering	(6,096)	—
Payment of deferred offering costs	—	(369)
Payment on capital lease obligations	—	(1)
Net cash provided by (used in) financing activities	80,268	(28)
Net increase (decrease) in cash and cash equivalents and restricted cash	31,832	(4,149)
Cash, cash equivalents and restricted cash, beginning of period	79,967	53,997
Cash, cash equivalents and restricted cash, end of period	$ 111,799	$ 49,848
Reconciliation of cash and cash equivalents and restricted cash to the balance sheets		
Cash and cash equivalents	$ 111,506	$ 49,505
Restricted cash	293	343
Total cash and cash equivalents and restricted cash	$ 111,799	$ 49,848
Supplemental disclosure of cash flow information		
Cash paid for interest expense	$ 104	$ —
Cash paid for operating leases	$ 656	$ —
Deferred offering costs included in accounts payable	$ —	$ 729
Deferred offering costs included in accrued and other current liabilities	$ —	$ 195

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

1. ORGANIZATION AND DESCRIPTION OF THE BUSINESS

Description of Business

Vera Therapeutics, Inc., (the "Company") is a clinical late-stage stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. The Company is headquartered in Brisbane, California and was incorporated in May 2016 in Delaware. In 2017, the Company acquired all of the outstanding shares of PNA Innovations, Inc. ("PNAi"), which was based in Woburn, Massachusetts.

Reverse Stock Split

On May 7, 2021, the Company filed a certificate of amendment to its fourth amended and restated certificate of incorporation to effect a 11.5869-for-one reverse stock split of its issued and outstanding Class A common stock. Adjustments corresponding to the reverse stock split were made to the ratio at which the Company's redeemable convertible preferred stock converted into Class A common stock. Accordingly, all share and per share amounts related to Class A common stock, stock options and restricted stock awards for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable to reflect the reverse stock split.

Initial Public Offering

On May 13, 2021, the Company's registration statement on Form S-1 for its initial public offering (the "IPO") was declared effective by the Securities and Exchange Commission (the "SEC"), and the shares of its Class A common stock commenced trading on the Nasdaq Global Select Market on May 14, 2021. The IPO closed on May 18, 2021, pursuant to which the Company issued and sold 4,350,000 shares of its Class A common stock at a public offering price of $11.00 per share. On May 20, 2021, the Company issued 652,500 shares of its Class A common stock to the underwriters of the IPO pursuant to the exercise of the underwriters' option to purchase additional shares. The Company received total net proceeds of $48.4 million from the IPO, after deducting underwriting discounts and commissions of $3.9 million, and offering costs of $2.8 million. Prior to the completion of the IPO, all shares of redeemable convertible preferred stock then outstanding were converted into 15,464,776 shares of Class A common stock and 309,238 shares of Class B common stock.

Follow-on Public Offering

On February 14, 2022, the Company completed a follow-on public offering pursuant to which the Company issued and sold 5,742,026 shares of its Class A common stock at a public offering price of $15.00 per share, including 748,959 shares of Class A common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. The Company received total net proceeds of approximately $80.0 million, after deducting underwriting discounts and commissions of $5.2 million, and offering costs of approximately $0.8 million.

Liquidity

Since inception, the Company devoted substantially all of its resources to its research and development efforts, pre-clinical studies and clinical trials, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. The Company has incurred recurring net operating losses since its inception and had an accumulated deficit of $141.1 million as of March 31, 2022. The Company had cash, cash equivalents and marketable securities of $150.9 million as of March 31, 2022, and has not generated positive cash flow from operations. The Company has funded its operations primarily through the issuance of common stock, redeemable convertible preferred stock, debt financing and convertible notes. Management expects to continue to incur losses and negative cash flows from operations for at least the next several years.

Management believes that the Company's cash, cash equivalents and marketable securities as of March 31, 2022 will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months subsequent to the issuance date of these financial statements. The Company intends to raise additional capital through public or private equity offerings or debt financing or other capital sources, which may include strategic collaborations or other arrangements with third parties in order to achieve its long-term business objectives. If the Company fails to obtain necessary capital when needed on acceptable terms, or at all, it could force the Company to delay, limit, reduce or terminate its product development programs, commercialization efforts or other operations.

2. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and applicable rules and regulations of the SEC regarding interim financial reporting. The U.S. dollar is the Company's functional and reporting currency.

Unaudited Interim Condensed Financial Statements

The accompanying condensed balance sheet as of March 31, 2022, and condensed statements of operations and comprehensive loss, condensed statements of cash flows, and condensed statements of redeemable convertible preferred stock and stockholders' equity for the three months ended March 31, 2022 and 2021, are unaudited. The balance sheet as of December 31, 2021, was derived from the audited financial statements as of and for the year ended December 31, 2021. The unaudited condensed financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2021 and in the opinion of management, reflect all adjustments consisting solely of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of March 31, 2022, and the condensed results of its operations and its cash flows for the three months ended March 31, 2022. The financial data and other information disclosed in these notes related to the three months ended March 31, 2022, are also unaudited. The condensed results of operations for the three months ended March 31, 2022, are not necessarily indicative of the results to be expected for the full year ending December 31, 2022, or any other period. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2021, included in the Company's final prospectus dated May 13, 2021, for the IPO filed with the SEC on May 17, 2021, pursuant to Rule 424(b)(4) relating to the Company's Registration Statement on Form S-1, as amended (File No. 333-255492).

Emerging Growth Company Status

The Company is an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (1) is no longer an emerging growth company or (2) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Use of Estimates

The preparation of the Company's financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed financial statements and the reported amounts of expenses during the reporting period. Management estimates that affect the reported amounts of assets and liabilities include the accrual of research and development expenses, restructuring liabilities, fair value of common stock and stock-based compensation expense, determination of incremental borrowing rate for operating leases, the valuation allowance for deferred tax assets, and fair value of marketable and non-marketable securities. The Company evaluates and adjusts its estimates and assumptions on an ongoing basis using historical experience and other factors. Actual results could differ materially from those estimates.

Deferred Offering Costs

Deferred offering costs consisting of legal, accounting and filing fees relating to the IPO are capitalized. The deferred offering costs were offset against the Company's IPO proceeds upon the closing of the IPO.

Concentrations of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains bank deposits in a federally insured financial institution and these deposits may exceed federally insured limits. The Company is exposed to credit risk in the event of default by the financial institution holding its cash and cash equivalents to the extent recorded in the balance sheet. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's current and potential future product candidates, uncertainty of market acceptance of the Company's product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals or sole-source suppliers. The Company relies on one supply chain for each of its product candidates. If any of the single source suppliers in any of the supply chains fails to satisfy the Company's requirements on a timely basis, it could suffer delays in its clinical development programs and activities, which could adversely affects is operating results.

The Company's product candidates require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed, or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic continues to evolve. The extent of the impact of the COVID-19 pandemic on the Company's business, operations, and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's development activities, planned clinical trial enrollment, future trial sites, contract research organizations, third-party manufacturers, and other third parties with whom the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, the Company is conducting business as usual, with necessary or advisable modifications to employee travel and with the Company's employees working remotely. The Company will continue to actively monitor the evolving situation related to the COVID-19 pandemic and may take further actions that alter the Company's operations, including those that may be required by federal, state or local authorities, or that the Company determines are in the best interests of its employees and other third parties with whom the Company does business. At this point, the extent to which the COVID-19 pandemic may affect the Company's business, operations and development timelines and plans, including the resulting impact on expenditures and capital needs, remains uncertain.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Cash equivalents consist of money market funds and are stated at fair value.

Marketable Securities

The Company holds investments in marketable securities, consisting of U.S. government securities. Marketable securities with stated maturities of three months or less from the date of purchase are classified as cash equivalents and those with stated maturities of greater than three months as marketable securities on the balance sheet. The Company designated these securities as available-for-sale to support current operations and are reported at estimated fair value, with unrealized gains and losses recorded in accumulated other comprehensive loss within stockholders' equity. Interest, amortization and accretion of purchase premiums and discounts on marketable debt securities are included in other income (expense), net, in the condensed statements of operations and comprehensive loss.

The cost of available-for-sale marketable securities sold is based on the specific identification method. Realized gains and losses on the sale of available-for-sale marketable securities are recorded in other income (expense), net.

The Company regularly reviews all of the marketable securities for decline in fair value to determine whether unrealized losses have resulted from credit loss or other factors. The review includes considerations for the cause of the impairment but is not limited to (i) the consideration of the cause of the decline, (ii) any currently recorded expected credit losses and (iii) the creditworthiness of the respective security issuers. A decline of fair value below cost basis is considered an other-than-temporary impairment if the Company has the intent to sell the security or it is more likely than not that the company will be required to sell the security before recovery of the entire cost basis. Regardless of the Company's intent or requirement to sell the security, an impairment is considered other-than-temporary if the Company does not expect to recover the entire cost basis. In those instances, an impairment charge equal to the difference between fair value and the cost basis is recorded in other income (expense), on the condensed statements of operations and comprehensive loss.

The amortized or accreted cost basis of the marketable securities approximates its fair value.

Restricted Cash

Restricted cash represents cash held by a financial institution as collateral for a letter of credit securing the Company's operating lease for office and laboratory space, which is classified within non-current assets on the condensed balance sheets.

Comprehensive Loss

Comprehensive loss consists of two components: net loss and other comprehensive loss. Other comprehensive loss refers to gains and losses that are recorded as an element of stockholder's equity and are excluded from net loss. For the three months ended March 31, 2022, other comprehensive loss consists of unrealized gains and losses on marketable securities.

Research and Development Costs

Research and development costs are expensed as incurred and consist primarily of employees' salaries and related benefits, including stock-based compensation and termination expenses for employees engaged in research and development efforts, allocated overhead including rent, depreciation, information technology and utilities, contracted services, license fees, and external expenses to conduct and support the Company's operations that are directly attributable to the Company's research and development efforts. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered.

Costs incurred in obtaining technology licenses including upfront and milestone payments incurred under the Company's licensing agreements are recorded as expense in the period in which they are incurred, provided that the licensed technology, method or process has no alternative future uses other than for the Company's research and development activities. Where contingent milestone payments are due to third parties under license or other agreements, the milestone payment obligations are recognized as expense when achievement of the contingent milestone is probable, which is generally upon achievement of the milestone.

Research Contract Costs and Accruals

The Company enters into various research and development and other agreements with commercial firms, researchers, and others for provisions of goods and services from time to time. These agreements are generally cancellable, and the related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates.

Stock-Based Compensation

The Company recognizes compensation expense based on estimated fair values for all stock-based payment awards made to the Company's employees, nonemployee directors and consultants that are expected to vest. The valuation of stock option awards is determined at the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the Company to make assumptions and judgements about the inputs used in the calculations, such as the fair value of the common stock, expected term, expected volatility of the Company's common stock, risk-free interest rate and expected dividend yield. The valuation of restricted stock awards is measured by the fair value of the Company's common stock on the date of the grant.

For all stock options granted, the Company calculated the expected term using the simplified method (derived from the average midpoint between the weighted average vesting period and the contractual term of the award) for "plain vanilla" stock option awards, as the Company has limited historical information to develop expectations about future exercise patterns and post vesting employment termination behavior. The estimate of expected volatility is based on comparative companies' volatility. The risk-free rate is based on the yield available on United States Treasury zero-coupon issues corresponding to the expected term of the award. The Company records forfeitures when they occur.

Prior to the IPO, the fair value of the shares of common stock underlying the stock options was determined by the board of directors with the assistance of management and input from an independent third-party valuation firm, as there was no public market for the common stock. The board of directors determined the fair value of the Company's common stock by considering a number of objective and subjective factors, including the valuation of comparable companies, sales of redeemable convertible preferred stock, the Company's operating and financial performance, the lack of liquidity of common stock, and general and industry specific economic outlook, amongst other factors. Subsequent to the IPO, the Company determines the fair value using the market closing price of its common stock on the date of grant.

The Company records compensation expense for service-based awards on a straight-line basis over the requisite service period, which is generally the vesting period of the award. The amount of stock-based compensation expense recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest.

Income Taxes

The Company did not record an income tax provision for the three months ended March 31, 2022 and 2021, as net operating losses have been incurred since inception. The net deferred tax assets generated from net operating losses are fully offset by a valuation allowance.

Net Loss Per Share Attributable to Common Stockholders

Net loss per share of common stock is computed using the two-class method required for multiple classes of common stock and participating securities based upon their respective rights to receive dividends as if all income for the period has been distributed. The rights, including the liquidation and dividend rights and sharing of losses, of the Class A and Class B common stock are identical, other than voting rights. As the liquidation and dividend rights and sharing of losses are identical, the undistributed earnings are allocated on a proportionate basis and the resulting net loss per share attributed to common stockholders is therefore the same for Class A and Class B common stock on an individual or combined basis.

Prior to the IPO, the Company’s participating securities included the Company’s redeemable convertible preferred stock, as the holders were entitled to receive noncumulative dividends on a pari passu basis in the event that a dividend is paid on common stock. The Company also considers any shares issued on the early exercise of stock options subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of redeemable convertible preferred stock, as well as the holders of early exercised shares subject to repurchase, did not and do not have a contractual obligation to share in losses of the Company, and therefore during periods of loss there is no allocation required under the two-class method.

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, adjusted for outstanding shares that are subject to repurchase.

Diluted net loss per share is computed by giving effect to all potentially dilutive securities outstanding for the period using the treasury stock method or the if-converted method based on the nature of such securities. For periods in which the Company reports net losses, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, because potentially dilutive shares are not assumed to have been issued if their effect is anti-dilutive.

Leases

The Company leases office and laboratory space under operating leases and determines if the arrangement is a lease at inception. These leases contain lease and non-lease components. Non-lease components include payments for maintenance, utilities, real estate taxes, and management fees. The lease and non-lease components are combined and accounted as a single lease component. Payments made under operating leases (net of any incentive received from the lessors) are recorded on a straight-line basis over the term of the lease.

These leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on information available at commencement date in determining the present value of lease payments. The incremental borrowing rate is a hypothetical rate based on the Company's understanding of what the credit rating would be in a similar economic environment. Operating leases are included in operating lease right-of-use assets and operating lease liabilities, current and non-current, on the balance sheets.

Leases may include one or more options to renew. The Company does not assume renewals in determination of the lease term unless the renewals are deemed to be reasonably assured. The lease agreements generally do not contain any material residual value guarantees or material restrictive covenants.

Restructuring Costs

Restructuring costs primarily consist of contract termination costs related to leases and employee termination costs. The Company recognizes restructuring charges when the liability has been incurred. Key assumptions in determining the restructuring costs include the terms and payments that may be negotiated to terminate certain contractual obligations, cease use date of leased property and equipment, and the timing of employees leaving the Company.

Accretion expenses related to restructuring costs are included in general and administrative expenses.

Fair Value Measurements

Fair value is defined as the exchange price to sell an asset or transfer a liability (exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Fair value should be based on the assumptions market participants would use when pricing the asset or liability. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability as of the measurement date.

Fair value measurements are classified and disclosed in one of the following three categories:

Level 1 – Quoted unadjusted prices for identical instruments in active markets.

Level 2 – Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all observable inputs and significant value drivers are observable in active markets.

Level 3 – Model derived valuations in which one or more significant inputs or significant value drivers are unobservable, including assumptions developed by the Company.

Fair value accounting is applied to all financial assets and liabilities that are recognized or disclosed in the condensed financial statements on a recurring basis. The Company's financial instruments consist of cash and cash equivalents, marketable securities, prepaid expenses and other current assets, accounts payable and accrued expenses. Cash and marketable securities are reported at their respective fair values on our condensed balance sheets. The remaining financial instruments are reported on our condensed balance sheets at cost, which approximate their fair value due to their short-term nature.

Money market funds are highly liquid investments that are actively traded. The pricing information for the Company's money market funds are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

The Company's non-marketable equity securities (Note 6) are measured at fair value using an option pricing valuation methodology. The option pricing methodology relies on risk-neutral valuation which calculates the value of an asset by discounting the expected value of its future payoffs at the risk-free rate of return. The fair value of the non-marketable equity securities is derived from quoted prices for similar instruments and observable inputs in active markets. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

There were no transfers between Levels 1, 2, or 3 for any of the periods presented. As of March 31, 2022, and December 31, 2021, the Company held $105.3 million and $73.8 million, respectively, in money market funds.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2019-12, *Income Taxes (Topic 740)*, Simplifying the Accounting for Income Taxes, related to simplifying the accounting for income taxes. The guidance eliminates certain exceptions from Accounting Standards Codification (ASC) 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The guidance also clarifies and simplifies other aspects of the accounting for income taxes. The guidance became effective for the Company beginning on the first quarter of 2021 on a prospective basis. The Company adopted this
standard on January 1, 2021, and it did not have a material impact on the Company's condensed financial statements or related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, subsequently amended by ASU 2018-10, ASU 2018-11, ASU 2018-20, ASU 2019-01 and ASU 2019-10, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessors and lessees of a contract. The new standard 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 a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification on the balance sheets. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. The Company adopted this standard on January 1, 2022, using the optional transition method, which allows for the prospective application of the standard. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the standard, which allowed the Company to carry forward historical lease classification, to not reassess prior conclusions related to initial direct costs, and to not reassess whether any expired or existing contracts are or contain leases. The Company also elected the practical expedient to not separate lease and non-lease

components for all leases. In connection with the adoption of the new guidance, the Company recognized $6.8 million of operating lease right-of-use assets and $8.5 million of operating lease liabilities and derecognized $1.6 million of restructuring lease liability, with immaterial effect to the statements of operations and comprehensive loss and cash flows.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date and to change how other-than temporary impairments on investment securities are recorded. The guidance is effective for the Company beginning on January 1, 2023, with early adoption permitted. The Company is currently evaluating the impact the standard may have on its condensed financial statements and related disclosures.

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848)*: Facilitation of the Effects of Reference Rate Reform on Financial Reporting. In response to concerns about structural risks of the cessation of London Interbank Offered Rate (LIBOR), the amendments in this ASU provide optional guidance for a limited time to ease the potential burden in accounting for (or recognizing the effect of) reference rate reform on financial reporting. The amendments in this ASU provide optional expedients and exceptions for applying GAAP to contracts, hedging relationships and other transactions affected by reference rate reform if certain criteria are met. The expedients and exceptions provided by this amendment do not apply to contract modifications made and hedge relationships entered into or evaluated after December 31, 2022. The amendments in this ASU are elective and are effective for all entities as of March 12, 2020 through December 31, 2022. The Company continues to evaluate contractual arrangements that reference LIBOR and the impact this standard will have on its condensed financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*. This standard simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance in ASC 470-20 that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. ASU 2020-06 is effective for the Company for annual reporting periods, and interim reporting periods within those annual periods, beginning after December 15, 2023, and early adoption is permitted. The Company is currently evaluating the impact this standard will have on its condensed financial statements and related disclosures.

3. OTHER FINANCIAL STATEMENT INFORMATION

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	March 31, 2022	December 31, 2021
Prepaid contract costs	$ 5,117	$ 320
Prepaid insurance	452	1,193
Prepaid recruiting fees	258	253
Prepaid rent	219	219
Prepaid follow-on financing costs	—	275
Prepaid audit fees	—	123
Other	759	480
Total prepaid expenses and other current assets	$ 6,805	$ 2,863

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	March 31, 2022	December 31, 2021
Accrued research and development contract costs	$ 5,200	$ 364
Accrued development milestone	2,000	2,000
Related party payable	1,640	1,022
Accrued payroll	460	1,458
Accrued legal fees	253	457
Accrued expenses and other	598	627
Total accrued expenses and other current liabilities	$ 10,151	$ 5,928

Related party payable represents amounts due to Ares Trading S.A. (“Ares”), an affiliate of Merck KGaA, Darmstadt, Germany, related to manufacturing technology and know-how transfer services performed for atacicept pursuant to the license agreement between the Company and Ares (see Note 12).

4. NEUBASE ASSET SALE

On January 27, 2021, the Company entered into an asset purchase agreement with NeuBase Therapeutics, Inc. (“NeuBase”), whereby the Company agreed to sell all assets relating to its investment in PNAi, including all inventory, machinery, intellectual property, goodwill, and licenses, and NeuBase agreed to assume certain related liabilities. The sale of the Company’s investment in PNAi closed on April 26, 2021. The Company received $0.8 million in cash and 308,635 shares of NeuBase common stock, with a fair market value of $1.8 million based on the closing price reported on the Nasdaq Capital Market on the date the sale closed. Of the total NeuBase shares issued to the Company, 162,260 were placed in escrow to secure certain obligations under the asset purchase agreement. In connection with the sale, the Company also assigned certain leases for research and laboratory equipment to NeuBase (see Note 13). The Company recognized a gain of $2.7 million on the sale of assets to NeuBase.

As of March 31, 2022, 54,070 NeuBase shares have been released from escrow.

5. MARKETABLE SECURITIES

Marketable securities are debt securities measured at fair value on a recurring basis and accounted for as available-for-sale. These securities are classified within Level 2 in the fair value hierarchy because the Company uses quoted market prices to the extent available or alternative pricing sources to determine fair value. Marketable securities have maturities less than one year as of the condensed balance sheet date.

Unrealized gains and losses are reported as a component of other comprehensive loss. Fair value of the debt securities totaled $39.4 million as of March 31, 2022. The Company did not hold marketable debt securities as of December 31, 2021.

The following table summarizes the unrealized gains and losses in the Company's investments in marketable securities (in thousands):

	As of March 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Level 2:				
US Government bonds	$ 39,444	$ 2	$ (14)	$ 39,432
Total marketable securities	$ 39,444	$ 2	$ (14)	$ 39,432

6. NON-MARKETABLE EQUITY SECURITIES

The Company has an investment in NeuBase common stock with restrictions on the sale or transfer of the shares. Fair value is determined using alternative pricing sources and models utilizing market observable inputs. The Company reports the restricted equity securities as non-marketable equity securities on the balance sheet and determines current or non-current classification based on the expected duration of the restriction.

The Company recorded a net unrealized loss of $0.3 million in other expense for the three months ended March 31, 2022. The carrying value is measured as the total initial cost, less the cumulative net unrealized loss. The carrying value of the non-marketable equity securities as of March 31, 2022, is summarized below.

Balance as of December 31, 2021	$ 867
Change in fair value	(287)
Balance as of March 31, 2022	$ 580

7. LEASES

Net lease cost recognized is summarized as follows (in thousands):

	Three Months Ended March 31,
Operating lease cost	$ 570
Sublease income	(482)
Net lease cost	$ 88

As of March 31, 2022, the maturities of the lease liabilities based on minimum lease commitment amount are as follows (in thousands):

Remainder of 2022	$ 1,981
2023	2,702
2024	2,742
2025	1,880
2026	-
Total minimum lease payments	9,305
Less: Imputed interest	(1,458)
Present value of operating lease liabilities	7,847
Less: Current portion of operating lease liabilities	2,490
Non-current operating lease liabilities	$ 5,357

During the three months ended March 31, 2022, there were no additions of operating or finance lease assets. As of March 31, 2022, the company had not executed any operating or finance leases that were yet to commence. As of March 31, 2022, the weighted-average remaining operating lease term was 3.4 years and the weighted-average discount rate was 9.0% for operating leases recognized in the financial statements.

In accordance with ASC 840, *Leases*, the aggregate minimum non-cancellable annual lease payments for operating leases in effect as of December 31, 2021, were as follows (in thousands):

	Operating Leases [1]	Sublease Income
2022	$ 2,669	$ 1,901
2023	2,755	1,964
2024	2,818	2,029
2025	1,954	1,569
Total minimum lease payments	$ 10,196	$ 7,463

(1) Future minimum lease payments include repayment of outstanding restructuring liabilities.

8. NOTE PAYABLE

Note payable consists of the following:

	Rate Type	Maturity	Effective Interest Rate	March 31, 2022	December 31, 2021
				(in thousands)	*(in thousands)*
Collateralized note	Variable	2026	9.54%	$ 5,000	$ 5,000
Less: Unamortized debt issuance costs				(63)	(77)
Net carrying amount of debt				$ 4,937	$ 4,923

The carrying amount of debt approximates fair value due to its variable interest rate.

In December 2021, the Company entered into a loan and security agreement (the Loan Agreement) for a non-revolving credit facility with borrowing capacity of up to $50.0 million. An initial $5.0 million (the Loan) was funded in December 2021, and an additional $45.0 million will be available in minimum draws of $5.0 million, at the Company's option through the end of 2022. The Loan matures in December 2026, which may be extended by 12 months subject to certain clinical data milestones. The debt facility provides for at least 48-months of interest-only payments, which may be extended to 60 months if the final maturity date is extended.

Initially, the Loan bears interest at 8.25%, with a floating interest rate tied to LIBOR. The Company is permitted to prepay the Loan, subject to certain conditions. Upon the maturity date or prepayment of the Loan, the Company is required to make a final payment equal to 5.0% (or 7.0% if the maturity date is extended) of the aggregate principal amount of the Loan. The Loan Agreement contains a subjective acceleration clause in the case of an event of default. If such a matter occurs and is continuing, the lender may legally demand the outstanding principal and interest immediately due and payable. There are no financial covenants associated with the credit facility and the Loan is secured by the Company's assets.

Principal installments due on the note subsequent to March 31, 2022, are as follows *(in thousands)*:

Remainder of 2022	$ —
2023	—
2024	—
2025	—
2026	5,000
Total long-term debt	$ 5,000

9. COMMON STOCK

As of March 31, 2022, the Company's amended and restated certificate of incorporation authorized the Company to issue 500,000,000 shares of Class A common stock and 14,600,000 shares of Class B common stock, each with a par value of $0.001 per share. Each share of Class A common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Class B common stock is non-voting. The holders of Class A common stock, voting exclusively and as a separate class, have the exclusive right to vote for the election of one director of the Company. Class A common stockholders and holders of Class B common stock are entitled to receive dividends, as may be declared by the board of directors. Through March 31, 2022, no cash dividends have been declared or paid.

10. STOCK COMPENSATION

In April 2021, the Company adopted the 2021 Employee Stock Purchase Plan ("ESPP") and the 2021 Equity Incentive Plan ("2021 EIP"), each of which became effective in connection with the IPO. The Company has reserved 421,476 and 3,242,762 shares of Class A common stock for future issuance under the ESPP and 2021 EIP, respectively.

The Company may not grant any additional awards under the 2017 Equity Incentive Plan ("2017 EIP"). The 2017 EIP will continue to govern outstanding equity awards granted thereunder. As of March 31, 2022, there were 1,863,512 shares available for issuance under the 2021 EIP.

2017 EIP and 2021 EIP

Stock option activity under the 2017 EIP and 2021 EIP was as follows:

	NUMBER OF OPTIONS	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	AGGREGATE INTRINSIC VALUE (000s)
Balance – December 31, 2021	2,924,521	$ 5.62	9.11	$ 61,712
Granted	588,002	21.08		
Exercised	(17,946)	3.65		
Cancelled and forfeited	—	—		
Outstanding as of March 31, 2022	3,494,577	8.23	9.03	$ 53,356
Options exercisable as of March 31, 2022	672,992	3.47	8.72	$ 13,472
Vested and expected to vest as of March 31, 2022	3,494,577	$ 8.23	9.03	$ 53,356

The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2022, was $0.3 million. The weighted-average grant date fair value of options granted during the three months ended March 31, 2022, was $14.08 per share.

ESPP

The ESPP enables eligible employees to purchase shares of the Company's Class A common stock at the end of each offering period at a price equal to 85% of the fair market value of the shares on the first trading day or the last trading day of the offering period, whichever is lower. Eligible employees generally include all employees. Share purchases are funded through payroll deductions of at least 1% and up to 15% of an employee's eligible compensation for each payroll period. The number of shares reserved for issuance under the ESPP increase automatically on the first day of each fiscal year, beginning on January 1, 2022, by a number equal to the lesser of 440,502 shares, 1% of the total number of shares of the Company's capital stock (including all classes of the Company's common stock) outstanding on the last day of the calendar month prior to the date of the increase, or such lower number of shares. (including no shares) approved by the Company's board of directors. As of March 31, 2022, 8,458 shares have been issued pursuant to the ESPP. The ESPP generally provides for six-month consecutive offering periods beginning on September 14, 2021. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation. As such, stock-based compensation expense has been recorded for the three months ended March 31, 2022.

Stock-Based Compensation Expense

The following tables summarize the stock-based compensation expense for stock options and restricted stock awards granted to employees and nonemployees that was recorded in the Company’s statements of operations and comprehensive loss for the three months ended March 31, 2022 and 2021.

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 902	$ 60
General and administrative	760	344
Total stock-based compensation expense	$ 1,662	$ 404

	Three Months Ended March 31,	
	2022	2021
Employees	$ 1,014	$ 399
Nonemployees	648	5
Total stock-based compensation expense	$ 1,662	$ 404

As of March 31, 2022, the Company had $17.1 million of unrecognized stock-based compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.93 years.

The fair value of stock options granted during the three months ended March 31, 2022 and 2021 was estimated using the Black-Scholes option pricing model based on the following weighted-average assumptions.

	Three Months Ended March 31,	
	2022	2021
Expected term (in years)	6.0 – 6.1	6.0 – 6.1
Expected volatility	75.8%	76.3% – 76.4%
Risk-free rate	1.8% –1.9%	0.6% – 0.8%
Dividend yield	—	—

Restricted Stock Awards

In October 2020, in conjunction with the Series C redeemable convertible preferred stock issuance, the Company restricted 49,636 shares of fully issued and outstanding Class A common stock held by the Company’s Chief Executive Officer and founder. The restriction allowed the Company to repurchase shares that have not vested. The vesting term of restricted stock was one year. Restricted stock awards fully vested in October 2021. The grant date fair value of the restricted shares was $6.37.

For the three months ended March 2022 and 2021, the Company recognized zero and $0.1 million, respectively, of stock-based compensation expense related to restricted stock awards that vested during the period.

Restricted Stock Units

The Company grants restricted stock units ("RSU") pursuant to the 2021 EIP and satisfies such grants through the issuance of the Company's common stock. The following table shows RSU activity for the period ending March 31, 2022.

	NUMBER OF OPTIONS	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE PER SHARE
Unvested balance at December 31, 2021	77,719	$ 23.99
Granted	—	—
Vested	(19,429)	23.99
Cancelled and forfeited	—	—
Unvested balance at March 31, 2022	58,290	8.23

As of March 31, 2022, the Company recognized $0.5 million of stock-based compensation for restricted stock units and the Company had $1.3 million of unrecognized stock-based compensation expense related to unvested restricted stock units, which is expected to be recognized over a weighted-average period of approximately 0.72 years.

11. EMPLOYEE BENEFIT PLANS

The Company sponsors a qualified 401(k) defined contribution plan covering eligible employees. Participants may contribute a portion of their annual compensation limited to a maximum annual amount set by the Internal Revenue Service. There were no employer contributions under this plan for the three months ended March 31, 2022.

12. LICENSES AND COLLABORATIONS

Ares Trading S.A.

In October 2020, the Company entered into a license agreement with Ares (the Ares Agreement), pursuant to which the Company obtained an exclusive worldwide license to certain patents and related know-how to research, develop, manufacture, use and commercialize therapeutic products containing atacicept, a recombinant fusion protein used to inhibit B cell growth and differentiation, which could potentially treat some autoimmune diseases.

As consideration for the Ares Agreement, the Company issued to Ares a non-refundable license issue fee of 22,171,553 shares of Series C redeemable convertible preferred stock resulting in Ares becoming a related party to the Company. The Series C redeemable convertible preferred stock had a deemed issuance price of $0.5918 per share, or $13.1 million in the aggregate.

In December 2020, the Company paid Ares a milestone payment of $25.0 million upon delivery and initiation of the transfer of specified information and materials. The Company is obligated to pay Ares aggregate milestone payments of up to $176.5 million upon the achievement of specified BLA filing or regulatory approval milestones and up to $515.0 million upon the achievement of specified commercial milestones.

The non-refundable license issue fee and milestone payment were recorded to research and development expense in the period incurred.

Ares is performing manufacturing technology and know-how transfer to the Company over a period not to exceed two years from the effective date of the Ares Agreement. The Company recorded related party expense of $1.1 million and $0.3 million to Ares for these services during the three months ended March 31, 2022 and 2021, respectively.

Commencing on the first commercial sale of licensed products, the Company is obligated to pay Ares tiered royalties of low double-digit to mid-teen percentages on annual net sales of the licensed products covered by the license. The Company is obligated to pay royalties on a licensed product-by-licensed product and country-by-country basis from the first commercial sale of a product in a country until the latest of (i) 15 years after the first commercial sale of such licensed product in such country; (ii) the expiration of the last valid claim of a licensed patent that covers such licensed product in, or its use, importation or manufacture with respect to, such country; and (iii) expiration of all applicable regulatory exclusivity periods, including data exclusivity, in such country with respect to such product. If the Company were to sublicense its rights under the Ares Agreement, the Company is obligated to pay Ares a percentage ranging from the mid-single-digit to the low double-digits of specified sublicensing income received.

Amplyx Pharmaceuticals Inc.

In December 2021, the Company entered into an asset purchase agreement (the Amplyx Agreement) with Amplyx Pharmaceuticals Inc. (Amplyx), a wholly owned subsidiary of Pfizer Inc. Pursuant to the terms of the Amplyx Agreement, the Company paid $5.0 million to Amplyx to purchase assets relating to an anti-BKV monoclonal antibody referred to as MAU868 for the treatment of BKV infection pursuant to a License Agreement between Amplyx and Novartis International Pharmaceutical AG (Novartis). In addition, the Company recognized a $2.0 million contingent milestone obligation that is probable of achievement as an assumed liability related to the asset purchase.

The transaction was treated as an asset acquisition, as the assets acquired did not meet the definition of a business. ASC 805-10-55 states that if substantially all the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the set is not considered a business. Since the gross assets acquired are concentrated on a single identifiable asset, MAU868, the transaction was accounted for as an asset acquisition. In accordance with accounting guidance, costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use. The assets purchased from Amplyx require substantial completion of research and development, regulatory and marketing approval efforts in order to reach technological feasibility. Accordingly, the acquisition cost of $7.0 million was recorded as research and development expense in the statement of operations and comprehensive loss on the acquisition date.

In connection with the Amplyx asset purchase, Amplyx assigned the Exclusive License Agreement between Amplyx and Novartis (the Novartis License) and Manufacturing and Supply Agreements to the Company. Under the Novartis License Agreement, the Company has exclusive worldwide rights from Novartis to develop, manufacture and commercialize MAU868. The Company will be solely responsible for all research, development, regulatory, manufacturing and commercialization activities of MAU868.

Under the Amplyx Agreement, the Company is obligated to make future milestone payments to Amplyx and Novartis totaling up to approximately $76.0 million, contingent upon the achievement of various clinical development and regulatory milestones. Of this total, the Company has recognized $2.0 million of future milestone payments to Novartis as assumed liabilities upon acquisition. In the event that MAU868 is commercialized, the Company is obligated to pay to Amplyx and Novartis royalties based on net sales by country and by product.

13. COMMITMENTS AND CONTINGENCIES

Facilities Leases

In November 2020, the Company entered into a non-cancellable sublease agreement for the facilities in South San Francisco, California, under the terms of which the Company is entitled to receive $7,925 in sublease payments over the term of the sublease, which ends concurrently with the original lease in September 2025. As tenant, the Company remains responsible for the minimum lease commitment on the facilities.

In November 2021, the Company entered a lease for approximately 4,900 square feet of office space for a term of 36 months in Brisbane, California. The base rent is approximately $0.3 million for the first year with scheduled annual 3% increases. The lease includes renewal options for the Company.

14. RESTRUCTURING AND RELATED ACTIVITIES

During the year ended December 31, 2019, the Company completely vacated its leased facilities in Woburn, Massachusetts. In connection with vacating the leased spaces, the Company recorded a discounted lease-related restructuring liability, which was calculated as the present value of the estimated future facility costs for which the Company would obtain no future economic benefit over the term of the lease, reduced for actual or estimated sublease rentals.

In July 2020, the Company initiated a restructuring plan to reduce operating expense as a result of the disposal of PNAi technology. The restructuring plan included reducing the number of employees, vacating leased facilities, and ceasing use of leased equipment.

As a result of this restructuring plan, the Company completely vacated its leased facilities in South San Francisco, California, which was subleased to a third party in November 2020, and returned certain leased equipment to the lessor. The Company recorded a discounted lease-related restructuring liability of $2.2 million and $0.8 million for the abandonment of the leased facilities and equipment, which was calculated as the present value of the estimated future lease costs for which the Company would obtain no future economic benefit over the term of the leases. In addition, the Company recognized restructuring liability of $321 related to severance and other employee termination costs related to the reduction in the number of employees.

The lease related restructuring liability of $1.6 million as of December 31, 2021, was derecognized upon the adoption of ASC 842 on January 1, 2022, and included in operating lease liabilities.

15. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following outstanding potentially dilutive shares were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented, because including them would have been anti-dilutive (on an as-converted basis).

	Three Months Ended March 31,	
	2022	2021
Redeemable convertible preferred stock	—	15,774,014
Class A common stock options issued and outstanding	3,494,577	2,015,523
Unvested restricted stock awards	—	28,955
Unvested restricted stock units	58,290	—
Total	3,552,867	17,818,492

16. RELATED PARTY TRANSACTIONS

In October 2020, the Company entered into the Ares Agreement with Ares, pursuant to which the Company obtained an exclusive worldwide license to certain patents and related know-how to research, develop, manufacture, use and commercialize therapeutic products containing atacicept, a recombinant fusion protein used to inhibit B cell growth and differentiation, which could potentially treat some autoimmune diseases. Related party transactions and balances in the current periods presented are described in Note 3 and Note 12.

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 unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 28, 2022 (the Annual Report).

Forward-Looking Statements

In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Overview

We are a late-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases. Our lead product candidate, atacicept, a self-administered fusion protein that blocks both B lymphocyte stimulator (BLyS) and a proliferation-inducing ligand (APRIL), is currently being evaluated for the treatment of immunoglobulin A nephropathy (IgAN) in the Phase 2b ORIGIN trial which we expect will complete enrollment in mid-2022 and report topline results in the fourth quarter of 2022. If the data from this trial are positive, we plan to initiate a pivotal Phase 3 clinical trial in 2023. We plan to initiate the Phase 3 COMPASS clinical trial of atacicept in lupus nephritis (LN), a severe manifestation of systemic lupus erythematosus (SLE), based on positive feedback from the FDA's review of promising clinical results in a Phase 2 clinical trial of atacicept in high disease activity patients with SLE. In December 2021, we obtained worldwide, exclusive development and commercial rights from Amplyx, a wholly owned subsidiary of Pfizer, to MAU868, a potentially first-in-class monoclonal antibody to treat BK virus (BKV) infections. We believe MAU868 is the only clinical-stage neutralizing monoclonal antibody that is directed against BKV, a polyoma virus that can have devastating consequences in certain settings such as kidney transplant and hematopoietic stem cell transplant. In an interim analysis of Phase 2 data in BK viremia among kidney transplant recipients, MAU868 was shown to be well tolerated and demonstrated a clinically significant reduction of virologic activity. We expect to share full results from the interim analysis in June 2022 and expect to initiate a Phase 2b or Phase 3 clinical trial in 2023. We believe that our current pipeline programs leverage the deep expertise of our team and have strong commercial synergies. We currently hold global rights to all of our pipeline programs.

Since our inception, we have devoted substantially all of our resources to our research and development efforts, pre-clinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations

We do not have any product candidates approved for commercial sale, and we have not generated any revenue from product sales. Our ability to generate revenue sufficient to achieve profitability, if ever, will depend on the successful development and eventual commercialization of one or more of our product candidates, which we expect, if they ever occur, will take a number of years. We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for nonclinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, we have funded our operations primarily through proceeds from the sale of shares of our Class A common stock, redeemable convertible preferred stock, debt financing and convertible promissory notes. As of March 31, 2022, we had $150.9 million in cash, cash equivalents and marketable securities. In May 2021, we completed our initial public offering (IPO) and issued 5,002,500 shares of Class A common stock for net proceeds of approximately $48.4 million, after deducting underwriting discounts and commissions, and offering related expenses. In February 2022, we completed a follow-on public offering and issued 5,742,026

shares of Class A common stock for net proceeds of approximately $80.0 million, after deducting underwriting discounts and commissions, and offering related expenses. We believe, based on our current operating plan, that our cash, cash equivalents and marketable securities as of March 31, 2022, will be sufficient to fund our operations for at least the next 12 months from the date of this Quarterly Report on Form 10-Q.

We have incurred significant operating losses since the commencement of our operations. Our net losses were $17.1 million and $4.7 million for the three months ended March 31, 2022 and 2021, respectively, and we expect to incur significant and increasing losses for the foreseeable future as we continue to advance our product candidates, atacicept and MAU868, to commercialization. Our net losses may fluctuate significantly from period to period, depending on the timing of expenditures on our research and development activities. As of March 31, 2022, we had an accumulated deficit of $141.1 million. Our primary use of cash is to fund operating expenses, which comprise research and development and general and administrative expenditures. Cash used to fund operating expenses depends on the timing of when we pay these expenses, as reflected in the changes in our working capital balances.

We expect to continue to incur net operating losses for at least the next several years, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- continue our ongoing and planned research and development of our product candidates, atacicept, for the treatment of IgAN and LN, and MAU868 for the treatment of BK viremia;
- conduct clinical trials and nonclinical studies for atacicept and MAU868;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how;
- attract, hire and retain additional clinical, scientific, quality control, and manufacturing management and administrative personnel;
- expand leased office facilities;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

We also expect to increase the size of our administrative function to support the growth of our business. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We will require substantial additional funding to develop our product candidates and support our continuing operations. Until such time that we can generate significant revenue from product sales or other sources, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which could include income from collaborations, strategic partnerships, or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot provide assurance that we will ever be profitable or generate positive cash flow from operating activities.

COVID-19 Pandemic

Since it was reported to have surfaced in December 2019, a novel strain of coronavirus (COVID-19) has spread across the world and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified and governments around the world, including in the United States, Europe and Asia, have implemented travel restrictions, social distancing requirements, stay-at-home orders and have delayed the commencement of non-COVID-19-related clinical trials, among other restrictions. As a result, the current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in financial markets.

As a result of the outbreak, many companies have experienced disruptions in their operations and in markets served. To date, we have initiated some and may take additional temporary precautionary measures intended to help ensure our employees' well-being and minimize business disruption. For the safety of our employees and their families, we have reduced the amount of time we expect our employees to spend onsite in our facilities. Certain of our third-party service providers have also experienced shutdowns or other business disruptions. We are continuing to assess the impact of the COVID-19 pandemic on our current and future business and operations, including our expenses, clinical trials and other development timelines, as well as on our industry and the healthcare system.

As a result of the COVID-19 pandemic, or similar pandemics and outbreaks, we have and may in the future experience severe disruptions, including:

- interruption of or delays in receiving products and supplies from the third parties on which we rely, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on our business operations by the local, state, or federal government;
- business disruptions caused by workplace, laboratory and office closures and an increased reliance on employees working from home, travel limitations, cybersecurity and data accessibility limits, or communication or mass transit disruptions; and
- limitations on employee resources that would otherwise be focused on the conduct of our activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the periods presented.

	Three Months Ended March 31,		CHANGE	
(dollars in thousands)	**2022**	**2021**	**AMOUNT**	**%**
Operating expenses:				
Research and development	$ 12,549	$ 2,932	$ 9,617	328 %
General and administrative	4,472	1,784	2,688	151 %
Total operating expenses	17,021	4,716	12,305	261 %
Loss from operations	(17,021)	(4,716)	(12,305)	261 %
Other income (expense):				
Interest income	26	2	24	*
Interest expense	(118)	—	(118)	*
Other income	315	—	315	*
Change in fair value of non-marketable equity securities	(287)	—	(287)	*
Total other income (expense)	(64)	2	(66)	*
Net loss and comprehensive loss	$ (17,085)	$ (4,714)	$ (12,371)	262 %

* Not meaningful

Research and Development Expenses

Research and development expenses represent a substantial portion of our operating expenses. Our research and development expenses consist primarily of direct and indirect expenses incurred in connection with the research and development of our product candidates. Direct expenses include costs incurred under agreements with third parties, including contract research organizations and

consultants directly related to our research and development of product candidates, laboratory supplies and costs of lab studies, and license and milestone fees incurred as a result of our contractual obligations for our development candidates. Indirect expenses include employee compensation and other personnel-related expenses, including stock-based compensation, facilities and depreciation related to buildings and equipment used for research and development personnel and activities and other expenses. From October 2020 until December 2021, we have been engaged in the development of atacicept as our sole product candidate. In December 2021, we entered into the Amplyx Agreement and acquired our second product candidate, MAU868.

Research and development expenses are recorded as expense in the period in which the related activities occurred, and payments we make prior to the receipt of goods or services to be used in research and development efforts are deferred as prepaid expenses until the goods or services are received and used. We accrue expenses for contract research and development as the related services are performed by monitoring the status of specified activities and billings received from our external service providers. These expenses are accrued based on estimates and are adjusted as actual expenses become known. The cost incurred in obtaining technology licenses, including initial and subsequent milestone payments incurred under our licensing agreements, are recorded as expense in the period in which they are incurred, as the licensed technology, method or process has no alternative future uses other than for our research and development activities. Where contingent milestone payments are due to third parties under license or other agreements, the milestone payment obligations are recognized as expense when achievement of the contingent milestone is probable, which is generally upon achievement of the milestone.

The following table summarizes our research and development expenses incurred during the respective periods.

	Three Months Ended March 31,		CHANGE	
(dollars in thousands)	**2022**	**2021**	**AMOUNT**	**%**
Direct research and development expenses				
Clinical trial expenses	$ 3,850	$ 1,176	$ 2,674	227 %
Contract manufacturing	6,014	299	5,715	1911 %
Consulting and professional services	1,081	808	273	34 %
Indirect research and development expenses				
Compensation and related benefits	1,506	590	916	155 %
Facilities and other	98	59	39	66 %
Research and development expenses	$ 12,549	$ 2,932	$ 9,617	328 %

* Not meaningful

Research and development expenses increased by $9.6 million, or 328%, to $12.5 million in the three months ended March 31, 2022, from $2.9 million in the three months ended March 31, 2021. The increase was primarily due to progressing clinical development of atacicept in IgAN and LN, including expenses incurred in manufacturing clinical supply for current and future clinical trials, and development expenses incurred for MAU868. Clinical trial expenses increased by $2.7 million due to patient screening and enrollment and clinical site activity in ORIGIN, startup activity for the COMPASS trial and expenses for the Phase 2a clinical trial of MAU868. Contract drug manufacturing increased by $5.6 million primarily due to expenses incurred to manufacture atacicept for clinical trials. Compensation and related expenses for research and development increased by $0.9 million due to increased headcount to support clinical development of atacicept and MAU86 during the current period.

We expect our research and development expenses to increase in future periods as we incur expenses to develop MAU868, plan and initiate the Phase 3 COMPASS trial of atacicept in LN and progress to later stages of development of atacicept in IgAN.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and personnel-related expenses, including stock-based compensation, for our personnel in executive management, legal, finance, human resources, and other administrative functions. General and administrative expenses also include professional fees paid for accounting, auditing, legal, tax and consulting services, and other general overhead costs to support our operations. General and administrative expenses are recorded as expense in the period they are incurred, and payments we make prior to the receipt of goods or services to be used for general and administrative purposes efforts are deferred as prepaid expenses until the goods or services are received and used.

	Three Months Ended March 31,		CHANGE	
(dollars in thousands)	**2022**	**2021**	**AMOUNT**	**%**
General and administrative	$ 4,472	$ 1,784	$ 2,688	151 %

General and administrative expenses increased by $2.7 million, or 151%, to $4.5 million in the three months ended March 31, 2022, from $1.8 million in the three months ended March 31, 2021, due primarily to increases of $0.7 million of payroll and related expenses including stock-based compensation, an increase of $0.7 million in insurance premium expense, $0.3 million recorded in the 2022 period due to the adoption of new accounting guidance for leases, an increase of $0.2 million in legal expenses, an increase of $0.2 million in audit and tax compliance expenses, and $0.2 million in expenses, including stock-based compensation, to consultants and non-employee directors.

Total Other Income (Expense)

	Three Months Ended March 31,		CHANGE	
(dollars in thousands)	**2022**	**2021**	**AMOUNT**	**%**
Total other income (expense)	(64)	$ 2	(66)	(3300)%

Total other expense increased by $66,000 to $64,000 in the three months ended March 31, 2022, from other income of $2,000 in the three months ended March 31, 2021, due to $287,000 of other expense recognized in the current period due to unrealized losses from non-marketable equity securities and $118,000 of interest expense related to $4.9 million of debt carried during the current period, partly offset by $315,000 of sublease income recognized due to the adoption of new accounting guidance for leases and increased interest income due to investments in marketable securities.

Liquidity and Capital Resources

To date, we have funded our operations primarily through proceeds from the sale of shares of our Class A common stock, redeemable convertible preferred stock, debt financing and convertible notes. From our inception through March 31, 2022, we have raised aggregate net cash proceeds of $275.0 million from the issuance and sale of redeemable convertible preferred stock, convertible notes, Class A common stock and our Loan Agreement with Oxford Finance LLC (Oxford). Since the date of our incorporation, we have not generated any revenue from product sales and have incurred substantial operating losses and negative cash flows from operations.

We use our cash to fund operations, primarily to fund our research and development efforts, clinical trials, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. Cash used to fund operating expenses is affected by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid assets.

We anticipate that we will continue to incur net losses for the foreseeable future as we continue research and development activities of atacicept and MAU868, hire additional staff, including clinical, operational, financial and management personnel, and incur additional expenses associated with operating as a public company. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our clinical development activities and our product candidate portfolio. We expect that our research and development and general and administrative costs will increase substantially as a result of our acquisition of MAU868, including in connection with conducting additional clinical trials and clinical trials for our research programs and product candidates, contracting with third parties to support nonclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

On May 18, 2021, we completed our IPO. In connection with our IPO, we issued and sold 5,002,500 shares of Class A common stock, including 652,500 shares associated with the full exercise on May 20, 2021 of the underwriters' option to purchase additional shares, at a price to the public of $11.00 per share, resulting in net proceeds to us of approximately $48.4 million, after deducting underwriting discounts and commissions and offering related expenses payable by us. All shares issued and sold were registered pursuant to a registration statement on Form S-1, as amended (File No. 333-255492), declared effective by the SEC on May 13, 2021.

In December 2021, we entered into the Amplyx Agreement, pursuant to which we paid $5.0 million to Amplyx to purchase assets relating to MAU868. Also in December 2021, we entered into the Loan Agreement with Oxford, pursuant to which we may borrow up to an aggregate maximum principal amount of $50.0 million, of which $5.0 million was funded on December 17, 2021, and the balance of which is available to be drawn between January 3, 2022, and December 31, 2022. See "—Loan and security agreement" below.

On February 14, 2022, we completed our follow-on public offering. In connection with our follow-on public offering, we issued and sold 5,742,026 shares of Class A common stock, including 748,959 shares associated with the full exercise of the underwriters'

option to purchase additional shares, at a price to the public of $15.00 per share, resulting in net proceeds to us of approximately $80.0 million, after deducting underwriting discounts and commissions and offering related expenses payable by us.

As of March 31, 2022, we had $150.9 million of cash, cash equivalents and marketable securities. We believe, based on our current operating plan, that our cash, cash equivalents and marketable securities as of March 31, 2022, will be sufficient to fund our operations for at least the next 12 months from the date of this Quarterly Report on Form 10-Q.

Cash Flows

The following table summarizes our cash flows for the periods indicated.

	Three Months Ended March 31,	
(dollars in thousands)	**2022**	**2021**
Net cash used in operating activities	$ (8,981)	$ (4,121)
Net cash used in investing activities	(39,455)	—
Net cash provided by (used in) financing activities	80,268	(28)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 31,832	$ (4,149)

Operating Activities

In the three months ended March 31, 2022, we used $9.0 million of cash in operating activities, attributable to a net loss of $17.1 million and a $3.9 million increase in prepaid expenses and other current assets, partially offset by a $5.9 million increase in accounts payable, a net $4.2 million increase in accrued and other current liabilities and $1.7 million of non-cash stock-based compensation expense.

In the three months ended March 31, 2021, we used $4.1 million of cash in operating activities, attributable to a net loss of $4.7 million, restructuring payments of $0.6 million and a decrease of $0.2 million in accounts payable, partially offset by a $1.1 million increase in accrued and other current liabilities and $0.4 million of non-cash stock-based compensation expense.

Investing Activities

In the three months ended March 31, 2022, our investing activities used $39.5 million of cash primarily resulting from the purchase of short-term marketable securities.

Financing Activities

In the three months ended March 31, 2022, our financing activities provided $80.3 million of cash resulting from $86.1 million proceeds from our follow-on offering, net of underwriting discounts and commissions, partially offset by the payment of $6.1 million of related offering costs during the period.

In the three months ended March 31, 2021, our financing activities used $28,000 of cash resulting from payments of $369,000 for deferred offering costs primarily related to our IPO, partially offset by proceeds of $342,000 from the exercise of stock options to purchase Class A common stock.

Contractual Obligations

During the three months ended March 31, 2022, there were no material changes to our contractual obligations and commitments from those described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report.

Loan and security agreement

On December 17, 2021, we entered into a loan and security agreement (the Loan Agreement) with Oxford, a Delaware limited liability company, as lender (Lender) and collateral agent. The Loan Agreement provides for a term loan (the Loan) in an aggregate maximum principal amount of $50.0 million, of which $5.0 million was funded on December 17, 2021 and the balance of which is available to be drawn between January 3, 2022 and December 31, 2022. The Loan is available in minimum draws of $5.0 million, entirely at our option and not contingent upon the completion of clinical, regulatory, financial or other related milestones.

The final maturity date of the Loan is December 17, 2026, which may, upon achieving either (i) positive Phase 2b clinical trial data of atacicept in IgAN or (ii) positive pivotal trial data of atacicept in LN, at our option, be extended by 12 months (the Maturity Date Extension). We are required to make monthly interest-only payments for 48 months (extended to 60 months if the Maturity Date Extension is exercised) followed by full amortization through maturity.

Initially, through December 30, 2021, the Loan incurred interest at a per annum rate of 8.254%. Thereafter, the Loan bears interest at a floating per annum rate (based on the actual number of days elapsed divided by a year of 360 days) equal to the greater of (i) 8.25% and (ii) the sum of (a) the greater of (x) the 30-day U.S. LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue and (y) 0.09%, plus (b) 8.16%. The Loan Agreement also provides for the selection of an alternative benchmark rate in the event of the discontinuance of LIBOR or any subsequent benchmark rate.

We are permitted to prepay the Loan in full or in part at any time upon 10 business days' written notice to the Lender, subject to the applicable Prepayment Fee (as defined below). Upon the earliest to occur of the maturity date, acceleration of the Loan or prepayment of the Loan, we are required to make a final payment equal to 5.0% (7.0% if the Maturity Date Extension is exercised) of the aggregate principal amount of the Loan (the Final Fee). Any prepayments of the Loan, whether mandatory or voluntary, must include an amount equal to the sum of (a) the portion of the outstanding principal of the Loan being prepaid plus accrued and unpaid interest thereon through the prepayment date, (b) the Final Fee, (c) the Lender's expenses and all other obligations that are due and payable to the Lender, and (d) a prepayment fee of (i) 3.0% of the portion of the Loan being prepaid if the repayment is on or before the first anniversary of the funding date of such term loan or (ii) 2.0% of the portion of the Loan being prepaid if the repayment is after the first anniversary of the funding date but on or before the second anniversary of the funding date of such term loan (the Prepayment Fee). There is no Prepayment Fee for any prepayments occurring after the second anniversary of the funding date of such term loan.

Our obligations under the Loan Agreement are secured by a security interest in all of our assets, other than our intellectual property, which is subject to a negative pledge. The Loan Agreement does not contain any financial related covenants. Included in the Loan Agreement are customary representations and covenants that, subject to exceptions, restrict our ability to, among other things: declare dividends or redeem or repurchase equity interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to our existing business.

Upon the occurrence of an event of default, a default interest rate of an additional 5.0% may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. Events of default under the Loan Agreement include customary events of default, including, but not limited to: (i) failure to (a) make any payment of principal or interest on its due date, or (b) pay any other obligations within three business days after such obligations are due and payable; (ii) failure to perform any obligation under specified covenants; (iii) the occurrence of a material adverse change; (iv) we or any of our subsidiaries being or becoming insolvent, beginning an insolvency proceeding, or becoming subject to an insolvency proceeding that is not dismissed or stayed within 45 days; (v) a default under any agreement with a third party resulting in a right by such third party to accelerate the maturity of any indebtedness in an amount in excess of $500,000 or that could reasonably be expected to have a material adverse change; (vi) the rendering of judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least $500,000 that remain unsatisfied, unvacated, or unstayed for a period of 10 days after the entry thereof; (vii) revocation, rescission, suspension or adverse modification of any governmental approval, or non-renewal of a governmental approval in the ordinary course for a full term, that could reasonably be expected to result in a material adverse change; and (viii) failure of a lien created under the Loan Agreement or any other loan document to constitute a valid and perfected lien on any of the collateral purported to be secured thereby, subject to no prior or equal lien, other than permitted liens.

Emerging growth company status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company under the JOBS Act until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenue of $1.07 billion or more, (ii) the date on which we have issued more than $1.0 billion of non-convertible debt instruments during the previous three fiscal years, (iii) the date on which we are deemed a "large accelerated filer" under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates, or (iv) December 31, 2026.

Critical Accounting Policies and Significant Judgments and Estimates

The discussion and analysis of our financial condition and results of operations is based on our unaudited condensed financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("GAAP"). The preparation of these unaudited condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities, at the date of the financial statements, as well as revenue and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies are described in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies, Significant Judgments and Use of Estimates" in our Annual Report on Form 10-K and the notes to our unaudited condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the three months ended March 31, 2022, there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents as of March 31, 2022, consisted of readily available checking and money market funds. Our marketable securities as of March 31, 2022, consisted of short-term marketable debt securities issued by the U.S. Treasury. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations. We do not believe that our cash, cash equivalents or marketable securities have significant risk of default or illiquidity. While we believe our cash, cash equivalents and marketable securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one financial institution that is in excess of federally insured limits.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (CEO) and chief financial officer (CFO), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based upon such evaluation, our CEO and CFO concluded that, as of March 31, 2022, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (SEC), and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

We identified no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended March 31, 2022, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. We are not currently a party to any material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors.

An investment in shares of our Class A common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to purchase, hold or sell shares of our Class A common stock. The occurrence of any of the risks described below could harm our business, financial condition, results of operations, growth prospects, and/or stock price or 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 consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that reflect changes from the similarly titled risk factors included in the Annual Report.

Risks related to our financial position and need for additional capital

We have not completed any clinical trials for our lead product candidate, atacicept, and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.*

We are a late-stage biotechnology company and we have no products approved for commercial sale, have not generated any revenue from product sales and have incurred losses since inception. To date, we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, executing partnerships, raising capital, acquiring, developing and securing our technology and product candidates, conducting the Phase 2b clinical trial of atacicept in patients with IgAN, preparing to initiate the Phase 3 clinical trial of atacicept in patients with LN, supporting clinical development of MAU868 and manufacturing atacicept and MAU868 clinical drug supply. We have not yet demonstrated our ability to successfully complete any clinical trials with respect to our product candidates, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult to accurately predict our future success or viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by late-stage biotechnology companies in rapidly evolving fields. We may face difficulty transitioning from a company with a research focus to a company capable of successfully executing drug development activities and supporting commercial operations. If we do not adequately address these risks and difficulties or successfully make such a transition, our business, financial condition, results of operations and prospects will be significantly harmed.

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

Developing treatments for immunological and inflammatory diseases, including conducting nonclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses will increase in connection with our ongoing activities, particularly as we continue to conduct clinical trials of, and seek marketing approval for, our product candidates. We anticipate incurring significant costs associated with the development of our product candidates. Our expenses could increase beyond expectations if we are required by the FDA, or any comparable foreign regulatory authority to perform clinical trials or nonclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for atacicept or MAU868, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We also will continue to incur costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of March 31, 2022, we had $150.9 million in cash, cash equivalents and marketable securities. In December 2021, we entered into the Loan Agreement with Oxford, providing us with up to $45.0 million of borrowing capacity after $5.0 million was funded at closing of the Loan Agreement in December 2021. We expect that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next 12 months. Our estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business, the ongoing COVID-19 pandemic and the macro-economic environment generally. We anticipate that our expenses will increase substantially if, and as, we:

- continue our ongoing and planned research and development of atacicept for the treatment of IgAN and LN;

- initiate or continue nonclinical studies and clinical trials for atacicept, MAU868 and any additional product candidates that we may pursue in the future;
- continue our ongoing and planned research and development of MAU868 for the treatment of BKV disease in kidney transplant recipients and other indications;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets, and know-how;
- acquire, develop or in-license other product candidates and technologies and further expand our clinical product pipeline;
- attract, hire and retain additional clinical, scientific, quality control, and manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

Advancing the development of atacicept, MAU868 and any future product candidates we may develop will require a significant amount of capital. Our existing cash and cash equivalents and net proceeds from our follow-on offering will not be sufficient to fund all of the activities that are necessary to complete the development of our product candidates through approval and commercial launch.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. Potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, including as a result of the COVID-19 pandemic, could also adversely impact our ability to access capital as and when needed. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

We have incurred net losses since inception, and we expect to continue to incur net losses for the foreseeable future. In addition, we may be unable to continue as a going concern over the long-term.*

We have incurred net losses in each reporting period since the commencement of our operations and have not generated any revenue from product sales to date. We had net losses of $17.1 million and $4.7 million for the three months ended March 31, 2022 and 2021, respectively. We had an accumulated deficit of $141.1 million as of March 31, 2022. Our losses have resulted principally from expenses incurred in research and development and from management and administrative costs and other expenses that we have incurred while building our business infrastructure, a significant portion of which were incurred resulting from our efforts to develop gamma-PNA chemistry and triplex gene editing for therapeutic use, which we discontinued in September 2020. Our lead product candidate, atacicept, is in clinical trials and MAU868 is in a Phase 2a clinical trial. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing our product candidates in one of our lead indications, we expect that we will continue to incur substantial research and development and other expenses as we continue the clinical development programs for our product candidates in other indications.

We expect to continue to incur increased expenses and operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval for our product candidates. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital. In any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

In addition, our condensed financial statements for the three months ended March 31, 2022 included elsewhere in this Quarterly Report have been prepared assuming we will continue as a going concern. However, we have incurred losses and negative cash flows

from operations. As a development stage company, we expect to incur significant and increasing losses until regulatory approval is granted for our product candidates. Regulatory approval is not guaranteed and may never be obtained. As a result, these conditions raise substantial doubt about our ability to continue as a going concern over the long-term.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, atacicept, MAU868 and any future product candidates we may develop. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate revenue from product sales depends heavily on our and our current and potential future collaborators' success in:

- completing clinical development of product candidates and programs and identifying and developing new product candidates;
- seeking and obtaining marketing approvals for any product candidates that we develop;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving adequate access and reimbursement by government and third-party payors for product candidates that we develop;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for product candidates that we develop, if approved;
- obtaining market acceptance of product candidates that we develop as viable treatment options;
- addressing any competing technological and market developments;
- maintaining our rights under our existing license agreement with Ares, Novartis and any similar agreements we may enter into in the future;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference, infringement or other intellectual property-related claims, if any; and
- attracting, hiring and retaining qualified personnel.

Even if atacicept, MAU868, or any future product candidate that we may develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to perform clinical trials or nonclinical studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not be able to reach or sustain profitability, and may need to obtain additional funding to continue operations.

The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In December 2021, we entered into the Loan Agreement with Oxford, providing us with up to $45.0 million of borrowing capacity after $5.0 million was funded at closing of the Loan Agreement in December 2021. Our overall leverage and certain obligations and affirmative and negative covenants contained in the related documentation could adversely affect our financial health and business and future operations by limiting our ability to, among other things, satisfy our obligations under the Loan Agreement, refinance our debt on terms acceptable to us or at all, plan for and adjust to changing business, industry and market conditions, use our available cash flow to fund future acquisitions and make dividend payments, and obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity.

If we default under the Loan Agreement, Oxford may accelerate all of our repayment obligations and exercise all of their rights and remedies under the Loan Agreement and applicable law, potentially requiring us to renegotiate our agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our Class A common stock to receive any proceeds from the liquidation. Oxford could declare a default upon the occurrence of customary events of default, including events that they interpret as a material adverse change as delineated in the Loan Agreement, payment defaults or

breaches of certain affirmative or negative covenants, thereby requiring us to repay the loan immediately. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our Class A common stock to decline. Additionally, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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

We are substantially dependent on the success of our product candidates, atacicept and MAU868, which are currently in the clinical development stage. If we are unable to complete development of, obtain regulatory approval for and commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Our future success is heavily dependent on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize our product candidates. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of atacicept in our ongoing clinical trials in patients with IgAN, as well as our efforts to evaluate atacicept in LN and MAU868 in kidney transplant recipients. We are investing significant efforts and financial resources in the research and development of our product candidates, which will require additional clinical development, evaluation of clinical, nonclinical and manufacturing activities, marketing approval from government regulators, and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote our product candidates before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. Should our planned clinical development of atacicept in patients with IgAN and LN, or MAU868 in kidney transplant recipients, fail to be completed in a timely manner or at all, we will need to rely on clinical development of atacicept or MAU868 in additional indications, which will require more time and resources to obtain regulatory approval and proceed with commercialization, and may ultimately be unsuccessful. We cannot assure you that our planned clinical development programs for our product candidates will be completed in a timely manner, or at all, or that we will be able to obtain approval for atacicept or MAU868 from the FDA or comparable foreign regulatory authorities. If we are unable to complete development of, obtain regulatory approval for and commercialize our product candidates in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. We have never completed a clinical trial or submitted a BLA to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business, financial condition, results of operations and prospects will be significantly harmed.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of nonclinical studies and early clinical trials may not be predictive of the results of subsequent clinical trials. We have a limited operating history and to date have not demonstrated our ability to complete large scale clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials. For example, atacicept has been the subject of clinical trials by prior sponsors, including a Phase 2 trial in SLE, that missed its primary endpoint in the overall study population. In the future, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or any potential future collaborator may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Any future delays or abandonment could harm our business, financial condition, results of operations and prospects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications.

Our future clinical trials may not be successful. If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business, financial condition, results of operations and prospects may be significantly harmed. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any

clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

We do not know whether our clinical trials will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. If we are unable to bring our product candidates to market, our ability to create long-term shareholder value will be limited.

In addition, we may rely in part on nonclinical, clinical and quality data generated by CROs and other third parties for regulatory submissions. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in nonclinical studies and clinical trials nonetheless failed to obtain FDA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA or foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit an application seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured, the terms of such approval may limit the scope and use, which may also limit commercial potential. Furthermore, the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA or comparable foreign regulatory authorities delaying, limiting or denying approval of a product candidate.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards (IRBs);
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- study conduct issues, which could confound the clinical endpoints and/or data;
- manufacturing sufficient quantities of clinical trial material to supply the clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- delays in enrollment due to low prevalence or incidence rates of subjects with the applicable disease;
- delays in enrollment by subjects, or completion of the trial by subjects, due to the COVID-19 pandemic;
- subjects choosing an alternative treatment or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- regulatory authorities imposing a clinical hold;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;

- shutdowns, either temporarily or permanently, of any facility manufacturing our product candidates or any of their components, including by order from the FDA or comparable foreign regulatory authorities due to violations of current good manufacturing practice (cGMP), regulations or other applicable requirements;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GCP) or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. For example, some hospitals delayed initiating clinical trials due to their focus on treating COVID-19 patients. Manufacturing timelines for drug product could be delayed, for example, due to a global shortage of syringes. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience delays in the completion of, or termination of, any clinical trial, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down development and approval processes and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval.

Any delays in our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize atacicept, MAU868 or any other product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of atacicept, MAU868 or other product candidates could be significantly reduced. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with IgAN and LN, the availability of competitive products, and significant competition for recruiting patients in clinical trials.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. In particular, as a result of the inherent difficulties in diagnosing IgAN, the availability of competitive products such as TARPEYO, and the significant competition for recruiting the limited number of patients who have the diseases for which our product candidates are being developed, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. Although we have engaged certain third-party investigators to assist with patient enrollment, there can be no assurance that we will be able to maintain our relationships with such third parties or that such third parties will be successful in helping us identify patients.

Factors that may generally affect patient enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites we enroll;

- competition with other companies for clinical sites or patients;
- the drug background and clinical experience (e.g., safety profile, risk/benefit assessment, mechanism of action, known proof of concept);
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- risk that enrolled participants will drop out before completion; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In addition, if any significant adverse events or other side effects are observed in any of our future clinical trials or other sponsor development programs of similar mechanism of action that may result in a drug class effect, it may make it more difficult for us to recruit patients to our clinical trials and patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, which would increase our costs and have an adverse effect on our company.

We may develop atacicept, MAU868 and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We may develop atacicept, MAU868 and future product candidates in combination with one or more currently approved therapies. Even if atacicept, MAU868 or 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 risks that the FDA or similar regulatory authorities outside of the United States 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.

We may also evaluate atacicept, MAU868 or any other future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell atacicept, MAU868 or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with atacicept, MAU868 or any other product candidate we develop, we may be unable to obtain approval of or market atacicept, MAU868 or any other product candidate we develop.

The incidence and prevalence for target patient populations of our product candidates in specific indications are based on estimates and third-party sources. If the market opportunities for atacicept, MAU868 or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in nonclinical or clinical trials.

The incidence and prevalence for target patient populations of our product candidates in specific indications are based on estimates and third-party sources. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance of our drugs by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to. If the market opportunities for atacicept, MAU868, or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve and sustain profitability might be materially and adversely affected.

Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. 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 or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Class A common stock.

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 our particular program, the approvability or commercialization of our 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 material or otherwise appropriate information to include in our disclosure.

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, our product candidates may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

We face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. The current standard-of-care for IgAN consists of treatment with RAAS inhibitors, including ACE inhibitors or ARBs, to control blood pressure, or steroids with or without other immunosuppressive agents to non-specifically reduce inflammation. Among emerging therapies, we consider our most direct competitors with respect to atacicept in IgAN to be the recently approved reformulated steroid from Calliditas Therapeutics AB, and programs in Phase 3 clinical development: Novartis Pharmaceuticals Corporation, Omeros Corporation, Travere Therapeutics, Inc., and Chinook Therapeutics Inc., and the following companies with programs in Phase 2 of clinical development: Chinook Therapeutics Inc., Alnylam Pharmaceuticals Inc., Apellis Pharmaceuticals, Inc., Reata Pharmaceuticals, Inc., RemeGen Co., Ltd., Visterra, Inc., Ionis Pharmaceuticals, Inc., Alexion Pharmaceuticals Inc. (Alexion), and DiaMedica Therapeutics, Inc. There is also a potential that SGLT2 inhibitors, including AstraZeneca plc's (AstraZeneca) Farxiga, which has completed Phase 3 clinical development, and C.H. Boehringer Sohn AG & Ko. KG's (Boehringer) jardiance, which is undergoing Phase 3 clinical development, will be approved broadly for chronic kidney disease and used in IgAN.

In LN, prior to December 2020, there had been no approved therapies, and the standard-of-care has consisted of a number of non-specific therapies, including MMF, steroids, cyclophosphamide, rituximab, calcineurin inhibitors, azathioprine, and hydroxychloroquine, dependent on class of disease and whether a patient was cycling through the induction or maintenance phase of therapy. We expect that these paradigms will evolve with the recent FDA approvals of GlaxoSmithKline plc's Benlysta (belimumab) and Aurinia Pharmaceuticals Inc.'s Lupkynis (voclosporin), both of which we consider to be direct competitors. Our competitors include: Roche Holding AG and Novartis Pharmaceuticals Corporation, each of which have programs in Phase 3 clinical development; and BeiGene Ltd., Janssen Pharmaceuticals, Inc., AstraZeneca, Alexion, Omeros Corporation, Kezar Life Science Inc., Bristol Myers Squibb, Boehringer, and Novartis Pharmaceuticals Corporation, each of which have programs in Phase 2 clinical development.

In the kidney transplant or HSCT setting, there are currently no anti-BKV therapies approved. The standard of care in both settings is to reduce immunosuppression as a first line, and potentially to offer intravenous immune globulin (IVIG) in kidney transplant recipients or antivirals with limited clinical evidence, including leflunomide and cidofovir, in either setting. There are few industry sponsored programs in development for these indications; we consider our closest competitor to be Memo Therapeutics AG's MTX-005, a monoclonal antibody targeting BKV which has recently commenced Phase 1 clinical trials. Additionally, Allovir's multi-virus specific T-cell therapy, Posoleucel, is in a Phase 2 clinical trial for BK viremia in kidney transplant recipients, a Phase 3 clinical trial for treatment of virus-associated cystitis, and a Phase 2 clinical trial in multi-virus prevention following allogeneic HSCT.

Many of our competitors have significantly greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have

significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or any future product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidates or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Changes in methods of manufacturing or formulation of our product candidates may result in additional costs or delays.

As our product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, and manufacturing sites are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. 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 commercialize our product candidates, if approved, and generate revenue.

Risks related to regulatory approval and other legal compliance matters

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business, financial condition, results of operations and prospects will be significantly harmed.

The time required to obtain approval by the FDA and comparable foreign authorities typically takes many years following the commencement of clinical trials. 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.

Applications for atacicept or MAU868 could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidate is not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval, resulting in a restrictive label and limiting commercial use;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials may not be sufficient to support the submission of a BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that the risk-benefit ratio for our proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

In addition, even if we obtain approval of our product candidates for a lead indication, regulatory authorities may not approve them for other indications, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy (REMS). Certain regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or may approve them with a label that does not include the labeling claims necessary or desirable for successful commercialization of our product candidates. In addition, if we are unable to obtain regulatory approval, or if regulatory approval results in a limited label, our business, financial condition, results of operation and prospects will be significantly harmed.

Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our product candidates would depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products, such as TARPEYO;
- the clinical indications for which the product candidate is approved;
- restrictions on use, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- our pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the availability of atacicept or MAU868 for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- inclusion or exclusion of our product candidates from treatment guidelines established by various physician groups;
- unfavorable publicity relating to our product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and accessible to patients. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from such product candidate and may not be able to achieve or sustain profitability.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage, such inability could significantly harm our business, financial condition, results of operations and prospects.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA or other regulatory authority investigation of the safety and effectiveness of

our product, our manufacturing processes and facilities or our marketing programs. FDA or other regulatory authority investigations could potentially lead to a recall of our product or more serious enforcement action, limitations on the approved indications for which it may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any product candidate, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could significantly harm our business, financial condition, results of operations and prospects.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of atacicept, MAU868 or any future product candidates we may develop. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, Merck KGaA, Darmstadt, Germany previously conducted APRIL-LN, a study aimed to evaluate the efficacy and safety of atacicept in patients with active LN, receiving newly initiated CS and MMF. Two weeks before the initiation of atacicept, significant decreases in immunoglobulin G (igG) levels began unexpectedly with initiation of MMF and high-dose CS, and persisted upon initiation of atacicept, which led to trial termination. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

If product candidates we develop are associated with undesirable side effects or have unexpected characteristics in nonclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete a trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may significantly harm our business, financial condition, results of operations and prospects.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our nonclinical studies or previous clinical trials. Our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if atacicept, MAU868 or any future product candidates we may develop, are used in combination with other therapies, atacicept, MAU868 or any future product candidates we may develop may exacerbate adverse events associated with the therapy and it may not be possible to determine whether it was caused by our product or the one with which it was combined. Patients treated with our product candidates may also be undergoing surgical, radiation, chemotherapy or other treatments, which can cause side effects or adverse events that are unrelated to our product candidates, but may still impact the success of our clinical trials. The inclusion of patients with advanced disease in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could significantly harm our business, financial condition, results of operations and prospects.

Further, toxicities associated with our products not seen during clinical testing may also develop after any approval, if obtained, and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies or early-stage clinical trials.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or other foreign regulatory authority grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the marketing approval of the product candidate in their countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our product is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if any product candidate we develop receives regulatory approval, it could be subject to significant post-marketing regulatory requirements and will be subject to continued regulatory oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the marketed product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve atacicept or MAU868, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or applicable foreign regulatory authorities approve atacicept, MAU868 or any product candidate we develop in the future, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize atacicept, MAU868, or any product candidate we may develop in the future, and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of atacicept, MAU868 or any product candidate we may develop in the future. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not be able to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If these actions impose constraints on FDA's or foreign regulatory authorities' ability to engage in oversight and implementation activities in the normal course, it may significantly harm our business, financial condition, results of operations and prospects.

We are currently seeking orphan drug designation for atacicept for the treatment of IgAN, but even if designated we may not ultimately realize the potential benefits of orphan drug designation.

We are currently seeking orphan drug designation from the FDA and European Medicines Agency for atacicept for the treatment of IgAN. Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States but where there is no reasonable expectation to recover the costs of developing and marketing a treatment drug in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. However, orphan drug designation neither shortens the development time nor regulatory review time of a product candidate nor gives the candidate any advantage in the regulatory review or approval process.

In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective. Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care.

Similarly, in Europe, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000. This applies to products that are intended for a life-threatening or chronically debilitating condition and either (1) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (2) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the EU to justify the necessary investment in its development. Moreover, in order to obtain orphan designation in the EU it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or, if such a method exists, the product will be of significant benefit to those affected by the condition. In the EU, orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and applicants can benefit from specific regulatory assistance and scientific advice. Products receiving orphan designation in the EU can receive 10 years of market exclusivity, during which time no "similar medicinal product" for the same indication may be placed on the market. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. However, the 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation—for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar medicinal product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the first marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or

- the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product.

If we do not receive or maintain orphan drug designation for atacicept for the treatment of IgAN, it could limit our ability to realize revenues.

Even though MAU868 has Fast Track designation from FDA for the prevention of BK virus disease in renal transplant and hematopoietic stem cell transplant, it may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that MAU868 will receive marketing approval.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition or disease, and nonclinical or clinical data demonstrate the potential to address an unmet medical need, the product may qualify for FDA Fast Track designation, for which sponsors must apply. The FDA has broad discretion whether or not to grant this designation. Although we have received Fast Track designation for the investigation of MAU868 for the prevention of BK virus disease in renal transplant and hematopoietic stem cell transplant recipients, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

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

We may in the future seek an accelerated approval for atacicept, MAU868 or future product candidates we may develop. For example, if the results from our Phase 2b trial of atacicept in patients with IgAN are positive, we may seek accelerated approval with the FDA based on this trial, which we may not be granted. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. For example, UPCR is an accepted surrogate primary endpoint for clinical trials in IgAN, which could allow for a faster path to commercialization than rate of change/slope in glomerular filtration rate (GFR). We may seek accelerated approval based on the UPCR endpoint. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. Use of the accelerated approval pathway would entail submission of a BLA under Subpart E of the FDA regulations with the UPCR surrogate endpoint data while conducting the Phase 3 trial to collect change/slope in GFR data. If granted, accelerated approval is usually contingent on the sponsor's agreement to complete ongoing trials and/or conduct, in a diligent manner, additional post-approval confirmatory studies to verity and describe the drug's clinical benefit. Additionally, unless and until converted to full approval at the time of satisfying the conditions of any accelerated approval letter, the sponsor must submit any promotional materials for the accelerated approval drug to FDA at least 30 days prior to use. Third-party payors may refuse to provide coverage or reimbursement for the drug until the confirmatory studies are complete. Additionally, if such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for atacicept or MAU868, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA, for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for atacicept, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for atacicept or MAU868 would result in a longer time period to commercialization of such product candidate, could increase the cost of development of atacicept or MAU868 and could harm our competitive position in the marketplace.

Biosimilars to our product candidates may provide competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act), signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk 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. 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 any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited.

Any product candidate we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

We intend to seek approval to market atacicept and MAU868 in both the United States, in the EU and in certain foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for atacicept or MAU868, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of atacicept or MAU868. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of a product candidate will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for the product candidate and may be affected by existing and future healthcare reform measures.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. If we obtain marketing approval of a product candidate, sales of such product will depend substantially, both in the United States and internationally, on the extent to which the costs of the product will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only at inadequate levels, we may not be able to successfully commercialize any product candidates we develop. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (CMS) an agency within the U.S. Department of Health and Human Services (HHS). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our product to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Governmental payors, as well as other third-party payors, including pharmacy benefit managers, have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our product. Nonetheless, atacicept, MAU868 or any future product candidates we may develop may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as atacicept, MAU868 or any future product candidates we may develop. In many countries, particularly the countries of the EU, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of atacicept, MAU868 or any future product candidates we may develop to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for atacicept, MAU868 or any future product candidates we may develop. Accordingly, in markets outside the United States, the reimbursement for any product that we commercialize may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates that we commercialize from third-party payors, the adoption of those products and potential sales revenue would be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for a product for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of atacicept, MAU868 or any future product candidates we may develop. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not be able to achieve or sustain profitability.

For example, the Affordable Care Act was passed in March 2010, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed 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; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government’s comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period coverage through the Affordable Care Act 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 Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is also unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act 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 Bipartisan Budget Act of 2018 and the Infrastructure Investments and Jobs Act, will remain in effect through 2030, unless additional congressional action is taken. COVID-19 pandemic relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations. In addition, Congress is considering additional health reform measures.

Moreover, 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 attempt to implement several of the administration's proposals. In response, the FDA concurrently released a final rule and guidance in September 2020, which went into effect on November 30, 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 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. As a result of litigation challenging the MFN Model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. Additionally, 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. However, the implementation of the rule has been delayed further by the Infrastructure Investments and Jobs Act until January 1, 2026. 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 Biden's 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 as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. 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 the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, achieve and sustain profitability or commercialize atacicept, MAU868 or any future product candidates we may develop. It is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for atacicept, MAU868 or future product candidates we may develop. 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; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of atacicept, MAU868 or future product candidates we may develop, 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.

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their implementing regulations, also imposes obligations, including mandatory contractual terms, certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health

information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state laws require biotechnology companies to report information on the pricing of certain drug products. Some state and local laws require the registration of pharmaceutical sales representatives.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU Member States, and the Bribery Act 2010 in the United Kingdom (UK). Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. 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 civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to stringent and evolving obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; harm to our business; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process personal information and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials, and sensitive third-party information. Our data processing activities subject us to numerous obligations relating to data privacy and security, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations that govern the processing of personal information by us and on our behalf. Data privacy and security obligations are evolving and may result in increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions, including monetary penalties and prohibitions on processing personal information that could require us to change our business practices. Interpretation of these obligations is likely to remain uncertain and potentially inconsistent for the foreseeable future. This evolution may create uncertainty in our business, affect our ability (or the ability of our third-party partners) to operate in

certain jurisdictions or to process personal information. This evolution could also necessitate the acceptance of more onerous obligations in our contracts and impose additional costs on us. Our efforts to bring our practices (and those of our third-party partners) into compliance with these obligations may not succeed for a variety of reasons, including due to internal or external factors such as resource allocation limitations or a lack of vendor cooperation. Noncompliance could result in the commencement of legal proceedings against us by governmental and regulatory entities, collaborators, data subjects or others. In addition, privacy advocates and industry groups have proposed, and may propose in the future, standards with which we are legally or contractually bound to comply.

Outside the United States, an increasing number of laws, regulations and industry standards apply to data privacy and security. For example, the GDP and UK GDPR apply strict requirements to the processing of personal information about clinical trials participants and other individuals in the EU and the UK, respectively. For instance, companies that violate the GDPR can face private litigation, prohibitions on data processing and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue. In addition, non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

Certain jurisdictions have enacted data localization laws and cross-border personal information transfer laws which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal information that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal information transfers may change or be invalidated. For example, the GDPR generally prohibits the transfer of personal information from the EEA to countries that the European Commission does not consider to provide adequate safeguards to protect the transferred personal information, such as the United States. The European Commission released a set of Standard Contractual Clauses that are designed to be a vehicle for such transfers. Currently, these Standard Contractual Clauses are a valid mechanism to transfer personal information outside of the EEA. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal information. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal information out of the EEA. Failure to comply with the GDPR or other law's cross-border data restrictions may increase our exposure to its heightened sanctions (such as regulatory actions and substantial fines), or injunctions against processing or transferring personal information from Europe or elsewhere. The inability to import personal information to the United States could significantly and negatively impact our business operations, including by restricting our clinical trial activities in Europe or elsewhere, limiting our ability to collaborate with third-party partners (such as contract research organizations and clinical trial sites) subject to certain data protection laws, or requiring us to increase our personal information processing capabilities and infrastructure in Europe and/or elsewhere at significant expense.

Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

In the United States federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws and consumer protection laws. For example, HIPAA imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, the California Consumer Privacy Act of 2018 (CCPA), which took effect on January 1, 2020, gives California residents certain rights similar to the individual rights given under the GDPR (including the right 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), and provides for civil penalties for violations.

Further, a new California privacy law, the California Privacy Rights Act (CPRA), creates additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). While certain clinical trials activities are exempt from the CCPA's requirements, other personal information that we handle may be subject to the CCPA, which may increase our compliance costs, exposure to regulatory enforcement action and other liabilities. Since the enactment of the CCPA, new privacy and data security laws have been proposed in many states and in the United States Congress, reflecting a trend toward more stringent privacy regulation in the United States that may increase our compliance costs and our exposure to liability. For example, Virginia passed the Consumer Data Protection Act and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our information processing practices and policies, divert resources from other initiatives and projects, including increased costs related to insurance, cybersecurity and information technology, and could restrict the way products and services involving data are offered, all of which could significantly harm our business, financial condition, results of operations and prospects. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third party partners (such as contract research organizations and clinical trial sites) may fail to comply with such obligations, which

could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could significantly harm our business, financial condition, results of operations or prospects.

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

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may 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 companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. 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-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials 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 or contractors, 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, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our product, or our failure to obtain any required import or export authorization for our product, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our product may create delays in the introduction of our product in international markets or, in some cases, prevent the export of our product to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be

imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or product targeted by such regulations, could result in decreased use of our product by, or in our decreased ability to export our product to existing or potential customers with international operations. Any decreased use of our product or limitation on our ability to export or sell access to our product would likely significantly harm our business, financial condition, results of operations and prospects.

We are subject to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others we do business with could subject us to substantial fines, penalties and even injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

We are subject to U.S. laws that regulate foreign investments in U.S. businesses and access by foreign persons to technology developed and produced in the United States. These laws include Section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the regulations at 31 C.F.R. Parts 800 and 801, as amended, administered by the Committee on Foreign Investment in the United States; and the Export Control Reform Act of 2018, which is being implemented in part through Commerce Department rulemakings to impose new export control restrictions on "emerging and foundational technologies" yet to be fully identified. Application of these laws, including as they are implemented through regulations being developed, may negatively impact our business in various ways, including by restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export our products, services, and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threatening monetary fines and other penalties if we do not.

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

The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our clinical trials.

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and since such time, actions taken around the world to help mitigate the spread of COVID-19 have included varying restrictions on travel, quarantines in certain areas, and forced closures for several types of public places and businesses The 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, such as travel, has fallen. The effects of government orders and our work-from-home could slow our productivity or disrupt our business in the future, 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. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices and limited the number of staff in any given research and development laboratory. As a result of the ongoing COVID-19 pandemic, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- 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;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical trial endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- limitations on our business operations by the local, state, or federal government that could impact our ability to sell or deliver our instruments and consumables;
- interruption of, or delays in receiving, supplies of atacicept or MAU868 from our contract manufacturing organizations (CMO) due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruption of or delays in receiving products and supplies from the third parties we rely on to, among other things, manufacture components of our instruments, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, which may impair our ability to sell our products and consumables;

- interruptions in nonclinical studies due to restricted or limited operations at our laboratory facility;
- business disruptions caused by workplace, laboratory and office closures and an increased reliance on employees working from home, travel limitations, cyber security and data accessibility limits, or communication or mass transit disruptions; and
- limitations on employee resources that would otherwise be focused on the conduct of our nonclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

Three vaccines for COVID-19 have been granted Emergency Use Authorization by the FDA as of May 2022, and more, including boosters, may be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials.

It is uncertain when restrictions will be fully lifted, and if so, when we will be able to resume pre-pandemic work routines. Imposition of government orders, including quarantine and shelter-in-place orders related to COVID-19 or other infectious diseases, is expected to continue to impact personnel at our and our third-party manufacturing facilities for the foreseeable future. The ongoing COVID-19 pandemic continues to evolve. The extent to which the COVID-19 pandemic continues to impact our business, clinical development, including our ongoing and planned preclinical studies and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease, including the effectiveness and timing of vaccination programs in the United States and worldwide. 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 effects could have negative impacts on our business, financial condition and results of operations.

In addition, to the extent the evolving COVID-19 pandemic continues to adversely affect our business 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.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including inflation and supply disruption. A domestic or global financial crisis can cause extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, which could result from an event like the COVID-19 pandemic or the recent global sanctions imposed by countries against Russia following Russia’s military intervention in Ukraine, could result in a variety of risks to our business, including disruption to enrollment within our ongoing clinical trials, our inability to purchase necessary supplies on acceptable terms, if at all, and our inability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees and key consultants.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams, including certain key consultants.

Furthermore, although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for all of our executives or employees. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities

and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize atacicept, MAU868 or any other product candidate will be limited and the potential for successfully growing our business will be harmed.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market atacicept, MAU868 or any product candidate we may develop in the future, we may not be able to successfully sell or market atacicept, MAU868 or any future product candidate we may develop in the future that obtained regulatory approval.

We currently do not have, and have never had, a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market atacicept, MAU868 or any future product candidate we may develop. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize atacicept, MAU868 or any product candidate we may develop in the future will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of atacicept, MAU868 or any product candidate we may develop in the future that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize atacicept, MAU868 or any product candidate we may develop in the future which may receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for a product candidate, which we may license to others, we will rely on the assistance and guidance of those collaborators. For any product candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

As an organization, we have never commercialized a product candidate. Factors that may affect our ability to commercialize our current or any future product candidate we may develop, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our current or any future product candidates we may develop and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of atacicept, MAU868 or any future product candidate we may develop. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our current or any future product candidate we may develop, we may not generate revenues from such product candidate or be able to achieve or sustain profitability.

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

As of March 31, 2022, we had 18 full-time employees, including 12 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we continue to operate as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and other comparable foreign regulatory agencies' review process for atacicept, MAU868 and any other future product candidates we may develop, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

In addition, we expect to be conducting multiple clinical trials of atacicept for several different indications concurrently, as well as MAU868 for the treatment of BKV disease in kidney transplant recipients. Given the small size of our organization, we may encounter difficulties managing multiple clinical trials at the same time, which could negatively affect our ability to manage growth of our organization, particularly as we take on additional responsibility associated with being a public company. Our future financial performance and our ability to successfully develop and, if approved, commercialize, atacicept, MAU868 and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of atacicept, MAU868 and any other future product candidates we may develop or otherwise advance our business. We cannot assure you that we will be able to manage our existing third party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize atacicept, MAU868 and any other future product candidates we may develop and, accordingly, may not achieve our research, development and commercialization goals.

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

Our headquarters is located in Brisbane, California, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have an adverse effect on our ability to conduct our clinical trials, our development plans and business.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act of 2017 (Tax Act) enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) signed into law on March 27, 2020, modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense. For example, proposals have recently been made in Congress to make various changes to the federal corporate income tax rules, although these have not yet been enacted. Among the changes made by the Tax Act were a reduction of the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”. We continue to examine the impact this tax reform legislation may have on our business. We urge investors to consult with their legal and tax advisers regarding the implications of the Tax Act and potential changes in U.S. tax laws on an investment in our Class A common stock.

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

We have incurred losses during our history, we expect to continue to incur significant losses for the foreseeable future, and we may never achieve profitability. As of December 31, 2021, we had federal and state net operating loss (NOL) carryforwards of $67.8 million and $35.7 million, respectively, that will begin expiring in the year 2032 and 2036, respectively, if not utilized. We also have $57.6 million of federal NOL carryforwards as of December 31, 2021, that do not expire as a result of recent tax law changes. Our

NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities. Our NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Under the Tax Act, as modified by the CARES Act, NOLs arising in tax years beginning after December 31, 2017, and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss, and NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, under the Tax Act as modified by the CARES Act, federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of current year taxable income for tax years beginning after December 31, 2020. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California has imposed limits on the usability of California state NOL carryforwards and certain tax credits to offset taxable income and tax, respectively, which after further recent legislation apply in taxable years beginning after 2019 and before 2022. It is generally uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. Our ability to utilize those NOLs could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have an adverse effect on our cash flows and results of operations.

A variety of risks associated with marketing our current or any future product candidate we may develop internationally could significantly harm our business, financial condition, results of operations and prospects.

We plan to seek regulatory approval of our current or any future product candidates we may develop outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

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

These and other risks associated with our international operations may significantly harm our business, financial condition, results of operations and prospects.

Risks related to our intellectual property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our and our current or future licensors', licensees' or collaborators' ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for atacicept, MAU868, and any

future product candidates that we may develop and technologies related to their various uses. We generally seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad related to our proprietary technologies, and their manufacture and uses that are important to our business, as well as inventions and improvements that are important to the development and implementation of our business. Our owned and in-licensed patents and patent applications in both United States and certain foreign jurisdictions relate to atacicept, MAU868, and other products. There can be no assurance that the claims of our owned or in-licensed patents, or any patent application that issues as a patent, will exclude others from making, using or selling our product candidates or any future product candidates or products that are substantially similar to our product candidates or any future product candidates. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We may seek to protect our proprietary position by acquiring or in-licensing additional relevant issued patents or pending applications from third parties. If we or our potential licensors, licensees or collaborators are unable to obtain or maintain patent protection with respect to atacicept, MAU868, and our other products, proprietary technologies and their uses, our business, financial condition, results of operations and prospects could be significantly harmed.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our owned or in-licensed patent applications or our current or future licensors', licensees' or collaborators' patent applications will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Moreover, in the future, some of our owned or in-licensed patents and patent applications may be co-owned with third parties. If we are unable to obtain exclusive licenses to any such co-owners' interest in such patents or patent applications, then such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Thus, the degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to atacicept, MAU868, or any future product candidates we may develop could significantly harm our business, financial condition, results of operations and prospects.

We cannot be certain that the claims in our U.S. pending patent applications and corresponding international applications will be considered patentable by the United States Patent and Trademark Office (USPTO) courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patent(s) will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting atacicept, MAU868, or any future product candidates we may develop by obtaining and defending patents. These risks and uncertainties include the following:

- patent applications must be filed in advance of certain events (e.g., third party filings, certain sales or offers for sale, or other activities that might be legally deemed to be public disclosures) and we might not be aware of such events or otherwise might not succeed in filing applications before they occur;
- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of

our research and development output before it is too late to obtain patent protection, for example, if patentable aspects are publicly disclosed, by us or a third party, such as by public use, sale or offer for sale, or publication.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Further, although we require our employees, commercial contractors, and certain consultants and investigators to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ, we cannot guarantee that we have entered into such agreements with each party, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach such agreements and claim ownership in intellectual property that we believe is owned or in-licensed by us. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Should any of the above events occur, it could significantly harm our business, financial condition, results of operations and prospects.

If we breach our license agreement with Ares, an affiliate of Merck KGaA, Darmstadt, Germany, related to atacicept, or the license agreement with Novartis related to MAU868, we could lose the ability to continue the development and commercialization of atacicept or MAU868, respectively.

We are dependent on patents, know-how and proprietary technology licensed or sublicensed to us from Ares and Novartis. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our and our licensor's proprietary technologies without infringing the proprietary rights of third parties. Either Ares or Novartis may have the right to terminate the applicable license agreement in full in the event we materially breach or default in the performance of any of the obligations under the applicable license agreement. A termination of either license agreement could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Additionally, certain patents, know-how and proprietary technology of third parties, including certain composition of matter patents, are sublicensed to us and in the event the applicable license agreement terminates, expires or is in dispute, it could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and Ares, an affiliate of Merck KGaA, Darmstadt, Germany, Novartis, or any future potential licensors, regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

In addition, we acquired worldwide, exclusive rights to atacicept pursuant to the Ares Agreement, and worldwide, exclusive rights to develop, manufacture and commercialize MAU868 pursuant to the Amplyx Agreement, pursuant to which we acquired Amplyx's right, title and interest in the license agreement between Amplyx and Novartis related to MAU868 (the Novartis Agreement). The Ares Agreement and Novartis Agreement are complex, and certain provisions 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 increase what we believe to be our financial or other obligations under such agreement, either of which could have an adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangement on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have an adverse effect on our business, financial conditions, results of operations, and prospects.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We may be required to make significant payments under our license agreements related to atacicept and MAU868.

Under the Ares Agreement, in consideration for the license, we issued 22,171,553 shares of our Series C redeemable convertible preferred stock to Ares at the time of the initial closing of our Series C redeemable convertible preferred stock financing in October 2020, which automatically converted into 1,913,501 shares of our Class A common stock upon the closing of our IPO. As additional consideration for the license, we paid Ares $25.0 million upon delivery and initiation of the transfer of specified information and materials and we are required to pay Ares aggregate milestone payments of up to $176.5 million upon the achievement of specified BLA filing or regulatory approval and aggregate milestone payments of up to $515.0 million upon the achievement of specified commercial milestones. Commencing on the first commercial sale of licensed products, we are obligated to pay tiered royalties of low double-digit to mid-teen percentages on annual net sales of the products covered by the license. In the event we sublicense our rights under the Ares Agreement, we are obligated to pay Ares a percentage ranging from the mid-single-digit to the low double-digits of specified sublicensing income received.

Under the Amplyx Agreement, we made an upfront initial payment of $5.0 million. We are also obligated to make certain milestone payments in an aggregate amount of up to $7.0 million based on the achievement of certain regulatory milestones. Further, we are required to pay Amplyx low single digit percentage royalties on net sales of MAU868 on a country-by-country and product-by-product basis. In addition, pursuant to the Novartis Agreement, we are obligated to make certain milestone payments in an aggregate amount of up to $69.0 million based on the achievement of certain clinical development, regulatory and sales milestones. Further, we are required to pay Novartis mid-to high-single digit percentage royalties based on net sales of MAU868 on a country-by-country and product-by-product basis. If milestone or other non-royalty obligations become due, we may not have sufficient funds available to meet our obligations, which will adversely affect our business operations and financial condition.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent positions of biotechnology companies generally are highly uncertain, involve complex legal and factual questions for which important legal principles remain unsolved and have been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect atacicept or MAU868 or which effectively prevent others from commercializing competitive technologies and product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Legal standards relating to valid and enforceable claim scope are unsettled in the United States and elsewhere and disputes challenging or re-defining scope are common in the biopharmaceutical industry. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether atacicept, or MAU868, or any future product candidates we may develop will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could significantly harm our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad.

The process by which patent applications are examined and considered for issuance as patents involves consideration by the relevant patent office of “prior art” relative to the invented technology. Different countries have different rules about what information or events can be considered “prior art,” and different requirements regarding when a patent application must be filed relative to any particular piece of potential prior art. Moreover, legal decisions can re-interpret or change whether particular information or events are considered to be “prior art.” Still further, in the United States, patent applicants are required to notify the USPTO of any material “prior art” of which they are aware for the patent examiner to consider in addition to independent searches that the patent examiner is required to do. Also, in the United States and certain other jurisdictions, third parties are entitled to submit prior art to patent offices for consideration during examination.

We may not be aware of certain relevant prior art, may fail to identify or timely cite certain prior art, or may not be able to convince a patent examiner that our patent(s) should issue in light of the art. Also, we cannot be certain that all relevant art will be or

was identified during examination of a patent application so that, even if a patent issues, it may be susceptible to challenge that it is not valid over art that was not considered during its examination.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or other jurisdictions, or become involved in post-grant challenges such as opposition, derivation, revocation, reexamination, post-grant review (PGR) and inter partes review (IPR), or other similar proceedings, or in litigation, challenging our patent rights, including by challenging the validity or the claim of priority of our patents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize atacicept, MAU868, or any future product candidates we may develop and compete directly with us, without payment to us. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of atacicept, MAU868, or any future product candidates we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, including art of which we were unaware, and art which was not raised during prosecution of any of our patents or patent applications. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would significantly impact our business, financial condition, results of operations and prospects. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates or could embolden competitors to launch products or take other steps that could disadvantage us in the marketplace or draw us into additional expensive and time consuming disputes. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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. For example:

- we may not be able to detect infringement of our issued patents;
- others may be able to develop products that are similar to atacicept, MAU868, or any future product candidates we may develop, but that are not covered by the claims of the patents that we may in-license in the future or own;
- our competitors may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell atacicept, MAU868, or any future product candidates we may develop;
- we, or our current or future collaborators or license partners, might not have been the first to make the inventions covered by the issued patents or patent applications that we may in-license in the future or own;
- we, or our current or future collaborators or license partners, might be found not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we may in-license in the future or own will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents, for which we are not aware;
- issued patents that we hold rights to may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- issued patents may not have sufficient term or geographic scope to provide meaningful protection;
- our competitors might conduct research and development activities 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;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets, and a third party may subsequently file a patent covering such intellectual property.

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

Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the patents and other proprietary rights of third parties. Claims by third parties that we infringe, misappropriate or otherwise violate their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement, misappropriation or other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. A finding by a court or administrative body that we infringe the claims of issued patents owned by third parties could preclude us from commercializing atacicept, MAU868, or any future product candidates we may develop.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import atacicept, MAU868, or any future product candidates we may develop and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology industry, including patent infringement lawsuits, and proceedings, such as oppositions, reexaminations, IPR proceedings and PGR proceedings, before the USPTO and/or corresponding foreign patent offices. In addition, many companies in intellectual property-dependent industries, including the biotechnology industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous third-party U.S. and foreign issued patents and pending patent applications may exist in the fields in which we are developing atacicept, MAU868, or any future product candidates we may develop. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of atacicept, MAU868, or any future product candidates we may develop.

It is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may be unable to develop, manufacture, market, sell and commercialize products or services or perform research and development or other activities covered by these patents. In the event that any of these patents were to issue and be asserted against us, we believe that we would have defenses against any such assertion, including that such patents are not valid. However, if such defenses to such assertion were unsuccessful, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents. We could also be required to obtain a license to such patents, which may not be available on commercially reasonable terms or at all. If we are unable to obtain such a license, we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents.

As the biotechnology industry expands and more patents are issued, the risk increases that atacicept, MAU868, or any future product candidates we may develop, may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of atacicept, MAU868, or any future product candidates we may develop, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that atacicept, MAU868, or any future product candidates we may develop may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Still further, we cannot rely on our experience that third parties have not so far alleged that we infringe their patent rights, as provisions of U.S. patent laws provide a safe harbor from patent infringement for therapeutic products under clinical development.

Any claims of patent infringement, misappropriation or other violations asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing atacicept, MAU868, or any future product candidates we may develop;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;

- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Any patent-related legal action against us claiming damages or seeking to enjoin commercial activities relating to our products, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market atacicept, MAU868, or any future product candidates we may develop. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or a future strategic partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign atacicept, MAU868, or any future product candidates we may develop processes to avoid infringement, if necessary.

An adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing atacicept, MAU868, or any future product candidates we may develop, which could significantly harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing atacicept, MAU868, and future product candidates and technologies.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have an adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights from third parties that we identify as necessary for future product candidates we may develop through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights.

While we may have in-licensed patents that cover atacicept and MAU868, it is possible that third parties may have blocking patents that prevent us from marketing, manufacturing or commercializing our patented products and practicing our in-licensed patented technology.

We may be unsuccessful in acquiring or in-licensing compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for practicing inventions claimed by our patents, including the manufacture, sale and use of atacicept, MAU868, and any future product candidates we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of 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. 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 have to abandon development of the relevant program or product candidate, which could significantly harm our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors or other third parties may infringe, misappropriate or otherwise violate our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement or other intellectual property claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we may in-license in the future or own is not valid, is unenforceable, and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our owned or in-licensed patents do not cover the technology in question. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at atacicept, MAU868, or any future product candidates we may develop, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability

assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would significantly harm our business, financial condition, results of operations and prospects.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

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

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our Class A common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could significantly harm our business, financial condition, results of operations and prospects.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have an adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring atacicept, MAU868, or any future product candidates to market. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. 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.

Further, the United States has enacted and implemented wide-ranging patent reform legislation and the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies (including atacicept and MAU868) would 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 and Europe. 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 subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

It is possible that we do not transfer or perfect ownership of all patents, patent applications or other intellectual property. This possibility includes the risk that we do not identify all inventors, or identify incorrect inventors, which may lead to claims disputing inventorship or ownership of our patents, patent applications or other intellectual property by former employees or other third parties. There is also a risk that we do not establish an unbroken chain of title from inventors to us. Errors in inventorship or ownership can sometimes also impact priority claims. If we were to lose ability to claim priority for certain patent filings, intervening art or other events may preclude us from issuing patents.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on atacicept, MAU868, or any future product candidates we may develop for an adequate amount of time.

Patents have a limited lifespan. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. Various extensions may be available, but there can be no assurance that any such extensions will be obtained, and the life of a patent, and the protection it affords, is limited. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. There is a risk that we may take action that detracts from any accrued patent term adjustment. Even if patents covering atacicept, MAU868, or any future product candidates we may develop are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our earliest in-licensed patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, prospects and results of operations.

Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

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 significantly harmed.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. 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 EU. 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 per approved drug product, and only those claims covering the approved drug product, 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 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 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 impacted and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

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

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These infringing products may compete with atacicept, MAU868, or any future product candidates we may develop, without any available recourse.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceutical products, it could be difficult for us to stop the infringement, misappropriation or violation of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and other proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. 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.

The ongoing conflict in Ukraine and related sanctions could significantly devalue our Russian and Eurasian patents. Recent Russian decrees may significantly limit our ability to enforce Russian patents. We cannot predict when or how this situation will change.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we 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 significantly harmed.

In addition, recordation of licenses with respect to exclusively licensed patent rights outside of the United States is potentially costly and we might fail to record such rights timely. If we fail to timely record our patent rights, third parties may try to seek licenses from the patent owners, or we may not be able to recover full damages for patent infringement in jurisdictions where we have no such recordations, any of which could significantly harm our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment, and other requirements imposed by regulations and governmental 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 governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or patent applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, potential competitors might be able to enter the market with similar or identical products or technology, which could significantly harm our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business, financial condition, results of operations and prospects could be significantly harmed.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business, financial condition, results of operations and prospects may be significantly harmed. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could significantly harm our business, financial condition, results of operations and prospects.

In addition, any proprietary name we propose to use with our current or future products 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 the 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 proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

If we are unable to protect the confidentiality of our trade secrets, our business, financial condition, results of operations, prospects and competitive position would be significantly harmed.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology or processes. Further, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, or claim ownership in intellectual property that we believe is owned or in-licensed by us. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, 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 from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. Many of our employees and consultants were previously employed at, may have previously provided or may be currently providing consulting services to, other biotechnology companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed 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 or patent applications. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing atacicept, MAU868, or any future product candidates or technologies we may develop. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, and cause us to lose valuable intellectual property rights or personnel, which could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can. 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. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have an adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We may enter into license agreements in the future with others to advance our research or allow commercialization of our product candidates. These and other licenses may not provide exclusive rights to use such 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 in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in our licenses.

If we fail to comply with our obligations under any such license agreements, including obligations to make various milestone payments and royalty payments and other obligations, the licensor may have the right to terminate the license. If these agreements are terminated, we could lose intellectual property rights that are important to our business, be liable for any damages to such licensors or be prevented from developing and commercializing our product candidates, and competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. Termination of these agreements or reduction or elimination of our rights under these agreements may also result in our being required to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business, including the payment of all applicable fees for patents covering our product candidates. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected. Further, we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control the prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by the actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and

technology. This could have an adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may need to obtain additional licenses from existing licensors and others to advance our research or allow commercialization of product candidates we develop. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could significantly harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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.

Disputes may arise between us and our past, current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are 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 significantly harm our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could significantly harm our business, financial condition and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could significantly harm our competitive position, business, financial condition and prospects.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We may develop, acquire, or license intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health

or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as march-in rights). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

Risks related to our dependence on third parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize atacicept, MAU868 or future product candidates we may develop and our business, financial condition, results of operations and prospects could be significantly harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our nonclinical studies and clinical trials and to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for atacicept and MAU868 in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Failure to comply and maintain adequate documentation with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to atacicept or MAU868 and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of atacicept or MAU868, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize atacicept or MAU868. As a result, our results of operations and the commercial prospects for atacicept and MAU868 would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely, and our business, financial condition, results of operations and prospects could be significantly harmed.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. In addition, our CROs could fail to perform, we could terminate their agreements or they could go out of business. If our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding CROs involves substantial cost and requires management time and focus, and could delay development and commercialization of atacicept, MAU868 or any future product candidate we may develop. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively 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 negative impact on our business and financial condition.

The COVID-19 pandemic and government measures taken in response have also had a significant impact on our CROs, and we expect that they will face further disruption which may affect our ability to initiate and complete our nonclinical studies and clinical trials.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional 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. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. There can be no assurance that we will not encounter challenges or delays with CROs in the future or that these delays or challenges will not significantly harm our business, financial condition, results of operations and prospects.

Prior to obtaining the rights to MAU868 from Amplyx, third parties had been responsible for all development activities. Although we believe the historical development activities were conducted in accordance with applicable rules and regulations in material respects, we cannot assure you that we will not discover inaccuracies or noncompliance in prior development activities that have an adverse effect on the future development of MAU868. For example, a regulatory authority may choose to inspect an investigational site and/or vendor such as a CRO for an MAU868 study that was previously conducted by Amplyx. Findings from such inspections could have an impact on the review of any future marketing applications by the FDA or foreign regulatory authorities.

In connection with our acquisition of MAU868, we have assumed the responsibility for ongoing clinical studies with MAU868, including related expenses and manufacturing and regulatory activities, which were previously managed and funded by Amplyx. This includes responsibility for the ongoing Phase 2 clinical trial of MAU868 for the treatment of BKV infection in kidney transplant recipients previously conducted by Amplyx. Any adverse events or reactions experienced by subjects in the trial may be attributed to MAU868 and may limit our ability to obtain regulatory approval with labeling that we consider desirable, or at all.

We contract with third parties for the manufacture of atacicept and MAU868 for our ongoing clinical trials, and expect to continue to do so for additional clinical trials of our product candidates and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of atacicept, MAU868 or other product candidates necessary for the development or commercialization of atacicept, MAU868 or such other product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for clinical trials under the guidance of members of our organization. We do not have long-term supply agreements for atacicept or MAU868. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our product candidates in the future will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

We expect to continue to rely on third-party manufacturers for the commercial supply of our product candidates, if we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- disruptions resulting from the impact of public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic);
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;

- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our 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 marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or other drugs necessary for the development or commercialization of our product candidates and significantly harm our business, financial condition, results of operations and prospects.

Furthermore, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or other drugs necessary for the development or commercialization of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our product for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide nonclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and significantly harm our business, financial condition, results of operations and prospects. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;

- the assumption of contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We may enter into collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of atacicept or MAU868.

In the future, we may partner with third-party collaborators for the development and commercialization of our product candidates. Our likely collaborators for any future collaboration arrangements would likely include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

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 revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators 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;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us 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 attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for 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; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

If we decide to establish collaborations in the future, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our current or any future product candidates we may develop will require substantial additional cash to fund expenses. We may continue to seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

If we seek collaborations in the future, we will face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a 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 or comparable foreign regulatory authorities, 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 drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidates. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

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. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into additional collaborations, we may not be able to negotiate 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 a 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 product revenue.

Risks related to ownership of our Class A common stock

An active, liquid and orderly trading market for our Class A common stock may not be developed or sustained.

Prior to the closing of our IPO in May 2021, no public market for shares of our Class A common stock existed. The trading market for our Class A common stock on the Nasdaq Global Market has been limited and an active trading market for our Class A common stock may never develop or be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our Class A common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of Class A common stock as consideration.

The price of our Class A common stock may be volatile, and you could lose all or part of your investment.*

The trading price of our Class A common stock has been, and is likely to be, highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. For example, the closing price of our Class A common stock since its trading began on May 14, 2021, to March 31, 2022, has ranged from a low of $11.30 to a high of $37.11. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our Class A common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report, these factors include:

- the timing and results of nonclinical studies and clinical trials of our current or any future product candidates we may develop or those of our competitors;
- regulatory actions with respect to our product candidate or our competitors' products;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- developments associated with our license with Ares, an affiliate of Merck KGaA, Darmstadt, Germany, including any termination or other change in our relationship with Ares or Merck KGaA, Darmstadt, Germany;
- developments associated with our license with Novartis, including any termination or other change in our relationship with Novartis or Amplyx;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our securities by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements; and
- general economic, industry and market conditions.

In addition, the trading prices for common stock of other biotechnology companies have been highly volatile as a result of factors unrelated to the specific company or its technology, as well as due to the COVID-19 pandemic. The COVID-19 outbreak continues to evolve. The extent to which the outbreak may impact our business, nonclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our Class A common stock.

If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Class A common stock.

Prior to our IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the audit of our financial statements as of and for the years ended December 31, 2019 and 2020, we identified a material weakness in our internal control over financial reporting. 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 financial statements will not be prevented or detected on a timely basis. The material weakness related to a lack of sufficient number of qualified personnel within our accounting function to adequately segregate duties, to perform sufficient reviews and approval of manual journal entries posted to the general

ledger and to consistently execute review procedures over general ledger account reconciliations, financial statement preparation and accounting for non-routine transactions.

We have implemented measures designed to improve our internal control over financial reporting which have remediated this material weakness, including the following:

- We have formalized our internal control documentation and strengthened supervisory reviews by our management; and
- We have added full-time and contract accounting personnel, and segregated duties amongst accounting personnel.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404) requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. We are not required to provide such management report until our annual report for our fiscal year ending December 31, 2022. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we are no longer an "emerging growth company," as defined in the JOBS Act, and are not a non-accelerated filer. We do not expect our independent registered public accounting firm to attest to our management report on internal control over financial reporting for so long as we are an emerging growth company.

If we identify any additional material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our Class A common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

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

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

- timing and variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- timing and status of enrollment for our clinical trials;
- impacts from the COVID-19 pandemic on us or third parties with which we engage;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if our current or any future product candidates we may develop receive regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidates;
- the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators;
- regulatory developments affecting atacicept, MAU868 or any future product candidate we may develop or those of our competitors; and
- changes in general market and economic conditions.

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

stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our principal stockholders and management own a significant percentage of our outstanding voting stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding capital stock, beneficially own a significant percentage of our outstanding voting stock. Therefore, these stockholders are able to significantly influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Class A common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their shares, and might affect the prevailing market price for our Class A common stock.

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

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

As of March 31, 2021, there were 26,756,235 shares of Class A common stock outstanding and held of record by 30 stockholders and 309,238 shares of Class B common stock outstanding and held of record by one stockholder. The number of record holders of our Class A common stock does not include DTC participants or beneficial owners holding shares through nominee names.

Further, certain holders of our Class A and Class B common stock have rights, subject to certain conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We have also registered all shares of Class A common stock that we may issue under our equity compensation plans. Such shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into Class A common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our Class A common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to atacicept, MAU868 or future product candidates we may develop on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to atacicept, MAU868 or future product candidates we may develop, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

We are an "emerging growth company," and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our Class A common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- 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;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our Class A common stock less attractive because we may rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) December 31, 2026.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have taken advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

Pursuant to Section 404 we will be required to furnish a report by our management on our internal control over financial reporting, including, if required by our filing status, an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company or a non-accelerated filer, 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 and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Additionally, we are also a "smaller reporting company," as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter.

Investors may find our Class A common stock less attractive as a result of our reliance on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

We do not currently intend to pay dividends on our Class A common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our Class A common stock.

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of the Loan Agreement between us and Oxford, dated December 17, 2021, restrict our ability to declare and pay dividends without the prior written consent of Oxford. Any return to stockholders will therefore be limited to any appreciation in the value of our Class A common stock, which is not certain.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay

in the future for shares of our Class A common stock, thereby depressing the market price of our Class A common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our amended and restated certificate of incorporations or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (DGCL), which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our Class A 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.

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 are 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 (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time);
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder);
- any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and

- any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants.

This choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

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 will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying such offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, 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.

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 the exclusive forum provision contained 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, financial condition, results of operations and prospects.

General risk factors

If our information technology systems or data, or those of any of our third-party partners (such as contract research organizations and clinical trial sites), are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties additional costs, loss of revenue or profits, significant liabilities, harm to our brand and material disruption of our operations, or otherwise harm our business.

In the ordinary course of our business, we may process proprietary, confidential and sensitive information, including personal information (such as health-related information, intellectual property and trade secrets (collectively, sensitive information). We may rely upon third-party service providers and technologies to operate critical business systems to process confidential and personal information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties.

The sensitive information processed in our technology systems, and those of our third party partners (such as contract research organizations and clinical trial sites) may be vulnerable to security incidents, which could result in unauthorized, unlawful, or accidental acquisition, loss, alteration, encryption, modification, destruction, damage, corruption, access, use, disclosure, or misappropriation of such sensitive information. Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. Threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts , we and our third party partners (such as contract research organizations and clinical trial sites) may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations. We and our third party partners may also be subject to a variety of evolving threats, including but not limited to errors or malfeasance by personnel, malware (including as a result of advanced persistent threat intrusions), malicious code (such as viruses and worms), software vulnerabilities, hacking, denial of service attacks (such as credential stuffing), social-engineering attacks (including phishing attacks), ransomware attacks, supply-chain attacks, server malfunctions, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods and other similar threats.

Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of information and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such

payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products) or the third-party information technology systems that support us and our services.

A security incident or other interruption could disrupt our ability (and that of our third-party partners (such as contract research organizations and clinical trial sites)) to provide our products. We may expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and information.

While we have developed systems and processes designed to protect the integrity, confidentiality and security of the sensitive information under our control, we cannot assure you that any security measures that we or our third party service providers have implemented will be effective in preventing cybersecurity incidents. There are many different cybercrime and hacking techniques and as such techniques continue to evolve, we may be unable to anticipate attempted security incidents, identify them before our information is exploited, or react in a timely manner. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems (including our products), our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Additionally, as a result of the ongoing COVID-19 pandemic, certain functional areas of our workforce remain in a remote work environment and outside of our corporate network security protection boundaries, which imposes additional risks to our business.

Despite our efforts to strengthen security and authentication measures, we have experienced an overall increase in cybersecurity incidents, none of which have caused material disruption to our business, or to our knowledge, involved a material security incident. However, we or our third-party partners (such as contract research organizations and clinical trial sites) could experience a security incident in the future, which could interrupt our operations disrupt our development programs and have a material adverse effect on our business, financial condition and results of operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the information. Likewise, we rely on third parties for the manufacture of our product candidates, to analyze clinical trial samples and to conduct clinical trials, and security incidents experienced by these third parties could have a material adverse effect on our business.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. Security incidents affecting us or our third-party partners (such as contract research organizations and clinical trial sites) could result in adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing information (including personal information); substantial remediation costs; litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be certain that our insurance coverage will be adequate or sufficient for data security liabilities actually incurred, will continue to be available to us on economically reasonable terms, or at all, or that 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.

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

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

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

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations— Recent accounting pronouncements."

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act the listing requirements of the Nasdaq Stock Market LLC and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be harmed.

These rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in SEC filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business, financial condition, results of operations and prospects.

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

The market price of our Class A common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation and shareholder derivative actions. We may be the target of these types of litigation and claims in the future. These claims and litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business, financial condition, results of operations and prospects.

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

The trading market for our Class A common stock is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

Use of Proceeds

We consummated our IPO pursuant to the registration statement on Form S-1, as amended (File No. 333-255492) that was declared effective on May 13, 2021, (the Registration Statement) and registered an aggregate of 5,002,500 shares of our Class A common stock. On May 18, 2021, we sold 4,350,000 shares of our Class A common stock at a public offering price of $11.00 per share for aggregate gross proceeds of $47.9 million. On May 20, 2021, in connection with the full exercise of the underwriters' 30-day option to purchase additional shares, we issued and sold 652,500 additional shares of Class A common stock at a public offering price of $11.00 per share for aggregate gross proceeds of $7.2 million. Jefferies LLC, Cowen and Company, LLC and Evercore Group L.L.C. served as joint book-running managers.

The net proceeds of our IPO were approximately $48.4 million, after deducting underwriting discounts and commissions of approximately $3.8 million and offering related expenses of approximately $2.8 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in the prospectus dated May 13, 2021, which forms a part of our Registration Statement. We invested the funds received in cash and cash equivalents in accordance with our investment policy.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
2.1^	Asset Purchase Agreement between the Registrant and Amplyx Pharmaceuticals, Inc., dated December 16, 2021 (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-262569), filed with the SEC on February 7, 2022).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 18, 2021).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 18, 2021).
4.1	Form of Class A Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-255492), filed with the SEC on May 10, 2021).
4.2	Second Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated October 29, 2020 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-255492), filed with the SEC on April 23, 2021).
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 amended, 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 amended, 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
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

* Filed herewith.
^ Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit (indicated by asterisks) have been omitted because such portions are both not material and are the type that the Registrant treats as private or confidential.
# The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (including this Quarterly Report on Form 10-Q), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

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.

Vera Therapeutics, Inc.

Date: May 16, 2022

By: /s/ Marshall Fordyce
Marshall Fordyce, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: May 16, 2022

By: /s/ Sean Grant
Sean Grant
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATIONS

I, Marshall Fordyce, certify that:

1. I have reviewed this Form 10-Q of Vera 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: May 16, 2022

By: /s/ Marshall Fordyce

Marshall Fordyce, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Sean Grant, certify that:

1. I have reviewed this Form 10-Q of Vera 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: May 16, 2022

By: /s/ Sean Grant

Sean Grant
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Vera Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 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 the best of 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: May 16, 2022

By: **/s/ Marshall Fordyce**

Marshall Fordyce, M.D.
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 Vera Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 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 the best of 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: May 16, 2022

By: **/s/ Sean Grant**

Sean Grant
Chief Financial Officer
(Principal Financial Officer)