Table of Contents

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, 2021

OR

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

For the transition period from to

Commission File Number: 001-39306

APPLIED MOLECULAR TRANSPORT INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-4481426**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1 Tower Place, Suite 850	
South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 650-392-0420

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AMTI	The Nasdaq Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of May 5, 2021, the registrant had 38,278,344 shares of common stock, $0.0001 par value per share, outstanding.

Table of Contents

Forward-Looking Statements

This report contains forward-looking statements that are based on our beliefs and assumptions and on information currently available to us. Forward-looking statements include information regarding our expectations on the timing of clinical study initiation and results and the timing and success of future development of our products, our possible or assumed future results of operations and expenses, business strategies and plans, trends, market sizing, competitive position, industry environment, potential growth opportunities, reliance on third parties, financing needs, and impact of the Affordable Care Act and other legislation, among other things. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “seeks,” “should,” “will,” “would” or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those described in “Risk Factors” and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Any forward-looking statement made by us in this report speaks only as of the date on which it is made. Except as required by law, we disclaim any obligation to update these forward-looking statements publicly, or to update the reasons. Actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (Unaudited)

Applied Molecular Transport Inc.
Condensed Balance Sheets
(unaudited)

(in thousands, except share and per share amounts)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 26,202	$ 5,843
Short-term investments	82,063	124,026
Prepaid expenses	2,648	1,311
Deferred offering costs	659	—
Other current assets	393	321
Total current assets	111,965	131,501
Property and equipment, net	6,999	8,447
Operating lease right-of-use assets, net	5,450	—
Finance lease right-of-use assets, net	796	—
Restricted cash	1,025	108
Other assets	169	127
Total assets	$ 126,404	$ 140,183
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,208	$ 3,174
Accrued expenses	4,094	4,173
Operating lease liabilities, current	2,377	—
Finance lease liabilities, current	235	—
Deferred rent, current	—	83
Capital lease obligations, current	—	232
Total current liabilities	8,914	7,662
Operating lease liabilities	3,589	—
Finance lease liabilities	344	—
Deferred rent	—	444
Capital lease obligations	—	404
Total liabilities	12,847	8,510
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.0001 par value, 450,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 35,250,650 and 35,121,360 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	4	4
Additional paid-in capital	273,348	271,000
Accumulated other comprehensive income	25	27
Accumulated deficit	(159,820)	(139,358)
Total stockholders' equity	113,557	131,673
Total liabilities and stockholders' equity	$ 126,404	$ 140,183

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

Applied Molecular Transport Inc.
Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 14,881	$ 12,954
General and administrative	5,599	2,489
Total operating expenses	20,480	15,443
Loss from operations	(20,480)	(15,443)
Interest income, net	40	83
Other (expense) income, net	(22)	49
Net loss	$ (20,462)	$ (15,311)
Net loss per share, basic and diluted	$ (0.58)	$ (2.06)
Weighted-average shares of common stock outstanding, basic and diluted	35,217,773	7,417,440
Comprehensive loss:		
Net loss	$ (20,462)	$ (15,311)
Other comprehensive (loss) income:		
Unrealized (loss) gain on investments	(2)	6
Total comprehensive loss	$ (20,464)	$ (15,305)

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

Applied Molecular Transport Inc.
Condensed Statements of Stockholders' Equity
(unaudited)
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
As of December 31, 2020	35,121,360	$ 4	$ 271,000	$ 27	$ (139,358)	$ 131,673
Exercise of common stock options	129,290	—	397	—	—	397
Stock-based compensation expense	—	—	1,951	—	—	1,951
Unrealized loss on investments	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	(20,462)	(20,462)
As of March 31, 2021	35,250,650	$ 4	$ 273,348	$ 25	$ (159,820)	$ 113,557

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

Applied Molecular Transport Inc.
Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit
(unaudited)
(in thousands, except share amounts)

	Convertible Preferred Stock						Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Series A		Series B		Series C							
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
As of December 31, 2019	5,157,213	$ 32,826	3,992,919	$ 30,921	4,816,160	$ 41,868	7,360,738	$ 1	$ 1,078	$ 13	$ (72,794)	$ (71,702)
Exercise of common stock options	—	—	—	—	—	—	73,594	—	58	—	—	58
Stock-based compensation expense	—	—	—	—	—	—	—	—	557	—	—	557
Unrealized gain on investments	—	—	—	—	—	—	—	—	—	6	—	6
Net loss	—	—	—	—	—	—	—	—	—	—	(15,311)	(15,311)
As of March 31, 2020	5,157,213	$ 32,826	3,992,919	$ 30,921	4,816,160	$ 41,868	7,434,332	$ 1	$ 1,693	$ 19	$ (88,105)	$ (86,392)

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

Applied Molecular Transport Inc.
Condensed Statements of Cash Flows
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2021	2020
Operating activities		
Net loss	$ (20,462)	$ (15,311)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,951	557
Depreciation and amortization	784	211
Non-cash operating lease expense	597	—
Net accretion of discounts on investments	(39)	—
Changes in operating assets and liabilities:		
Prepaid expenses	(1,337)	(2,321)
Other current assets	(114)	(563)
Other assets	—	504
Accounts payable	(1,331)	2,575
Accrued expenses	(389)	629
Operating lease liabilities	(608)	—
Deferred rent	—	6
Capital lease obligations	—	2
Net cash used in operating activities	(20,948)	(13,711)
Investing activities		
Proceeds from sales and maturities of investments	42,000	18,126
Purchases of property and equipment	(79)	(1,203)
Purchases of investments	—	(8,315)
Net cash provided by investing activities	41,921	8,608
Financing activities		
Proceeds from exercise of common stock options	397	58
Principal payments on finance lease liabilities	(57)	—
Payments of issuance costs for follow-on offering	(37)	—
Payments of issuance costs for initial public offering	—	(1,695)
Principal payments on capital lease obligations	—	(20)
Net cash provided by (used in) financing activities	303	(1,657)
Net increase (decrease) in cash, cash equivalents and restricted cash	21,276	(6,760)
Cash, cash equivalents and restricted cash, beginning of period	5,951	12,835
Cash, cash equivalents and restricted cash, end of period	$ 27,227	$ 6,075
Supplemental cash flow data:		
Cash paid for interest on capital lease obligations	$ 9	$ 1
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment included in accounts payable and accrued expenses	$ 54	$ 660
Issuance costs included in accounts payable and accrued expenses	$ 622	$ 641

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

Applied Molecular Transport Inc.
Notes to the Condensed Financial Statements
(unaudited)

1. Business and Principal Activities

Description of Business

Applied Molecular Transport Inc. (the Company) is a clinical-stage biopharmaceutical company leveraging its proprietary technology platform to design and develop a pipeline of novel oral biologic product candidates to treat autoimmune, inflammatory, metabolic, and other diseases. The Company is building a portfolio of oral product candidates based on its technology platform including its most advanced product candidate, AMT-101, a gastrointestinal (GI)-selective oral fusion of interleukin-10 (IL-10) and our proprietary carrier molecule that has completed a Phase 1b clinical trial in patients with ulcerative colitis (UC). The Company has initiated multiple Phase 2 clinical trials of AMT-101 in UC and related inflammatory indications. The Company's second product candidate, AMT-126, is a GI-selective oral fusion of interleukin-22 (IL-22) and the Company's proprietary carrier molecule currently in development for diseases related to intestinal epithelium (IE) barrier function defects driven by activation of the innate immune system. The Company's technology platform enables it to design and develop various oral biologic therapeutic modalities, such as peptides, proteins, full-length antibodies, antibody fragments, and ribonucleic acid (RNA) therapeutics, with potentially significant advantages over existing marketed and development-stage drugs.

Since the date of incorporation in Delaware on November 21, 2016, the Company has devoted substantially all of its resources to research and development activities, including research activities such as drug discovery, preclinical studies, and clinical trials as well as development activities such as the manufacturing of clinical and research material, establishing and maintaining an intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

Initial Public Offering

On June 4, 2020, the Company's registration statement on Form S-1 (File No. 333-238464) relating to its initial public offering (IPO) of common stock became effective. The IPO closed on June 9, 2020 at which time the Company issued an aggregate of 12,650,000 shares of its common stock at a price of $14.00 per share which included 1,650,000 shares of common stock issued in connection with the full exercise by the underwriters of their option to purchase additional shares of common stock. In addition, immediately prior to the closing of the IPO, all outstanding shares of the Company's convertible preferred stock automatically converted into 13,966,292 shares of common stock. The aggregate offering price for shares sold in the IPO was $177.1 million. After deducting underwriting discounts and commissions of $12.4 million and offering costs paid or payable by the Company of $4.1 million (including offering costs of $0.2 million paid in 2019), the net proceeds from the offering were approximately $160.6 million.

Follow-On Offering

On April 6, 2021, the Company completed a follow-on offering. See Note 10.

Liquidity and Capital Resources

Management believes that its existing cash, cash equivalents, and investments as of March 31, 2021 will be sufficient to allow the Company to fund its current operating plan through at least 12 months after the date of issuance of these condensed financial statements.

The Company has incurred significant losses and negative cash flows from operations since its inception. As of March 31, 2021, the Company had an accumulated deficit of $159.8 million and does not expect positive cash flows from operations in the foreseeable future. The Company expects to incur significant and increasing losses until regulatory approval is granted and successful commercialization is achieved for any of its product candidates. Regulatory approval is not guaranteed and may never be obtained. The Company has historically financed its operations primarily through private placements of its convertible preferred stock and sale of common stock upon the completion of both its IPO which was completed in June 2020 and its follow-on offering which was completed in April 2021. The Company may seek to raise capital through debt financings, private or public equity financings, license agreements, collaborative agreements or other arrangements with other companies, or other sources of financing. There can be no assurance that such financing will be available or will be at terms acceptable to the Company.

Risks and Uncertainties

The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, such as the duration of the outbreak, 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 and to address its impact, including on financial markets or otherwise. Beginning the week of March 16th, 2020, certain workforce of the Company began working from home. Disruptions caused by the COVID-19 pandemic, including the effects of the stay-at-home orders and work-from-home policies, may impact productivity, may result in increased operational expenses, certain adjustments to the operations of the Company's clinical trials, the suspension of enrollment of new patients at the Company's clinical trial sites, delays in activating new clinical trial sites, and delays in certain supply chain activities and collecting and analyzing data from patients in the Company's clinical trial, and may further disrupt the business and delay the development programs and regulatory timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct business in the ordinary course. As a result, research and development expenses and general and administrative expenses may increase significantly if there is an increased impact from COVID-19 on the costs and timing associated with the conduct of the clinical trials and other related business activities and as the Company implements mitigation strategies to offset the impact of the pandemic on development programs and regulatory timelines. The Company is carefully monitoring the pandemic and the potential length and depth of the resulting economic impact on our financial condition and results of operations.

2. Summary of Significant Accounting Policies

Condensed Financial Statements (Unaudited)

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) and applicable rules and regulations of the U.S. Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in financial statements prepared in accordance with GAAP have been condensed or omitted. The interim condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal, recurring adjustments that are necessary to present fairly the Company's results for the interim periods presented. The condensed balance sheet as of December 31, 2020, is derived from the Company's audited financial statements. The results of operations during the three months ended March 31, 2021, are not necessarily indicative of the results to be expected for the year ending December 31, 2021, or for any other future annual or interim period.

The accompanying interim unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2020, which are included in the Company's Annual Report on Form 10-K, filed with the SEC on March 19, 2021.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates on historical experience and market-specific or other relevant assumptions that it believes are reasonable under the circumstances. Assets and liabilities reported in the Company's condensed balance sheet and expenses and income reported are affected by estimates and assumptions, which are used for, but are not limited to, estimating research and development expenses and determining the fair value of assets and liabilities, including common stock valuation, income tax uncertainties, and measurement of stock-based compensation expense. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of the COVID-19 pandemic. Actual results could differ from such estimates or assumptions.

Concentration 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, cash equivalents, and investments. The Company invests in U.S. Treasury securities. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash, cash equivalents, and investments to the extent recorded in the condensed balance sheet. The Company has not experienced any losses on its deposits of cash, cash equivalents, and investments. The Company is subject to a number of risks similar to other early-stage biopharmaceutical companies, including, but not limited to, the need to obtain adequate additional funding, possible failure of current or future preclinical studies or clinical trials, its reliance on third parties to conduct its clinical trials, the need to obtain regulatory and marketing approvals for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's product

candidates, protection of its proprietary technology, and the need to secure and maintain adequate manufacturing arrangements with third parties. If the Company does not successfully commercialize or partner any of its product candidates, it will be unable to generate product revenue or achieve profitability.

Operating Segment

The Company operates and manages its business as one reportable and operating segment, which is the business of designing and developing a pipeline of novel oral biologic product candidates to treat autoimmune, inflammatory, metabolic, and other diseases. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance.

Cash and Cash Equivalents

Cash and cash equivalents are held in accounts at financial institutions. Such deposits have and will continue to exceed federally insured limits in the foreseeable future. The Company considers all highly liquid investments purchased with original maturities of 90 days or less from the purchase date to be cash equivalents. Cash equivalents consist of amounts invested in money market funds exclusively composed of U.S. government obligations.

Restricted Cash

The Company has cash in two collateral accounts related to letters of credit issued on behalf of the Company for the security deposits on the leased and subleased properties in South San Francisco. As of March 31, 2021, the collateralized cash in connection with the letter of credit was classified as restricted cash on the condensed balance sheet based on the terms of the agreements. The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed statements of cash flows (in thousands):

	March 31, 2021	March 31, 2020
Cash and cash equivalents	$ 26,202	$ 5,967
Restricted cash	1,025	108
Total cash, cash equivalents and restricted cash	$ 27,227	$ 6,075

Investments

The Company's investments have been classified and accounted for as available-for-sale securities. Fixed income securities consist of U.S. Treasury securities. The specific identification method is used to determine the cost basis of fixed income securities sold. These securities are recorded on the condensed balance sheets at fair value. Unrealized gains and losses on these securities are included as a separate component of accumulated other comprehensive income or loss. The cost of investment securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in other income or expense, net. The Company classifies its investments as short or long term primarily based on the remaining contractual maturity of the securities.

Property and Equipment, Net

Property and equipment are presented at cost, net of accumulated depreciation. Depreciation is recorded using the straight-line method. Depreciation begins at the time the asset is placed in service. Maintenance and repairs are charged to expense as incurred and costs of major replacement or improvement are capitalized. The Company's estimated useful lives of its property and equipment are as follows:

Laboratory and manufacturing equipment	5 years
Computer and office equipment	3 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Impairment of Long-Lived Assets

The Company evaluates the carrying amount of its long-lived assets whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss is recognized when the remaining book value of an asset is not recoverable. There was no impairment on long-lived assets during the three months ended March 31, 2021 and March 31, 2020.

Leases

In February 2016, the Financial Accounting Standards Board (FASB) issued a new standard that requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. The Company adopted the new standard on January 1, 2021 using the modified retrospective approach. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the condensed statements of operations and comprehensive loss.

At the inception of an arrangement, the Company determines if an arrangement is, or contains, a lease based on the facts and circumstances present in that arrangement. Lease classification, recognition, and measurement are then determined at the lease commencement date. For arrangements that contain a lease, the Company (i) identifies lease and non-lease components, (ii) determines the consideration in the contract, (iii) determines whether the lease is an operating or finance lease; and (iv) recognizes lease ROU assets and liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses the incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Most leases include options to renew and, or terminate the lease, which can impact the lease term. The exercise of these options is at the Company's discretion. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options.

The Company has operating leases for its corporate offices, laboratory and warehouse facilities, and a contract research organization (CRO) embedded lease arrangement. Fixed lease payments on operating leases are recognized over the expected term of the lease on a straight-line basis. Variable lease expenses that are not considered fixed are recognized as incurred. Fixed and variable lease expense on operating leases is recognized within operating expenses within our condensed statements of operations and comprehensive loss.

The Company has finance leases for lab equipment. Fixed payments on finance leases are recognized using the effective interest method. Finance lease ROU asset amortization and interest expense are recorded within operating expenses and interest income, net, respectively, within our condensed statements of operations and comprehensive loss.

The Company has elected the short-term lease exemption and, therefore, does not recognize an ROU asset or corresponding liability for lease arrangements with an original term of 12 months or less.

Research and Development Expenses

Research and development expenses are expensed as incurred. Research and development expenses include personnel costs related to research and development activities, materials costs, external clinical drug product manufacturing and clinical trial costs, outside services costs, repair, maintenance and depreciation costs for research and development equipment, as well as facility costs for laboratory space used for research and development activities.

Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical studies, clinical trials, manufacturing and development, within accrued expenses which are significant components of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, CROs and contract development and manufacturing organizations (CDMOs). The Company's contracts with the CROs and CDMOs generally include fees such as clinical trial fees, initiation fees, reservation fees, costs related to animal studies and safety tests, verification run costs, materials and reagents expenses, taxes, etc. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on estimates

of actual work completed in accordance with the respective agreements. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress, stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services.

If the actual timing of the performance of services or the level of effort varies from the estimate, the Company adjusts accrued expenses or prepaid expenses accordingly, which impact research and development expenses. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to the Company's prior estimates of research and development expenses.

Stock-Based Compensation Expense

The Company maintains both an equity incentive plan and an employee stock purchase plan (ESPP) as long-term incentives for its employees, consultants, and directors. The equity incentive plan allows for the issuance of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock grants, and restricted stock units. The ESPP has an offering period of two years comprised of four purchase periods. The ESPP allows employees to purchase shares of the Company's common stock each purchase period based on a percentage of their compensation subject to certain limits. As of March 31, 2021, no stock appreciation rights, restricted stock grants, restricted stock units or performance-based awards were issued.

The Company accounts for stock-based compensation expense by measuring and recognizing compensation expense for all share-based payments made to employees and non-employees based on estimated grant-date fair values. The grant-date fair values for options are recorded as stock-based compensation expense on a straight-line basis over each recipient's requisite service period, which is generally the vesting period. The grant-date fair values for the ESPP are recorded as stock-based compensation expense on a straight-line basis over the applicable purchase period. The Company recognizes actual forfeitures by reducing the stock-based compensation expense in the same period as that forfeitures occur.

The Company estimates the fair value of stock options granted to employees and non-employees using the Black-Scholes model. The Company estimates the fair value of ESPP for each purchase period at the beginning of the offering period using the Black-Scholes model. The Black-Scholes model requires the input of assumptions, including expected volatility, expected dividend yield, expected term and the risk-free rate of return. The fair value of ESPP also factors in a discount which is typically 15% of the purchase price as well as a call output and a put output of the Black-Scholes model.

Fair Value Measurement

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date. Fair value measurement establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value.

The Company determined the fair value of financial assets and liabilities using the fair value hierarchy that describes three levels of inputs that may be used to measure fair value, as follows:

- Level 1—Quoted prices in active markets for identical assets and liabilities;
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of March 31, 2021 and December 31, 2020, fair value measurements consisted mainly of cash equivalents and investments. The carrying amounts of these instruments approximate their fair value.

Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive (loss) income for the period. Other comprehensive (loss) income represents unrealized (loss) or gain on investments.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting and filing fees, are capitalized and subsequently offset against offering proceeds. During the three months ended March 31, 2021, $0.7 million of deferred offering costs were incurred in connection with the Company's follow-on offering which is described in Note 10.

Emerging Growth Company Status

The Company is an emerging growth company (EGC) as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act) and may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts EGCs from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards.

Commitments and Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources are recorded if and when it is probable that a liability has been incurred and the amount can be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update (ASU) 2016-02, *Leases (Topic 842)* that requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements.

The Company adopted the new standard on January 1, 2021 using the modified retrospective approach. The Company has elected to apply the transition method that allows companies to continue applying the guidance under the lease standard in effect at that time in the comparative periods presented in the condensed financial statements and recognize a cumulative-effect adjustment to the opening balance of accumulated deficit on the date of adoption. The Company has elected to combine lease components (for example fixed rent payments) with non-lease components (for example, common-area maintenance costs) on our facility, lab equipment and CRO embedded lease asset classes. The Company also elected the "package of practical expedients", which permits the Company not to reassess under the new standard the Company's prior conclusions about lease identification, lease classification and initial direct costs. Lastly, the Company elected a practical expedient to use hindsight in determining the lease term for all its leases.

Results for reporting period beginning after January 1, 2021 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. Upon adoption of the new lease standard, on January 1, 2021, the Company capitalized operating lease ROU assets of $6.0 million, with opening adjustments of $0.5 million related to deferred rent existing at transition, and $6.5 million of operating lease liabilities, within our condensed balance sheets upon adoption. There was no impact to the finance lease ROU asset and the finance lease liabilities upon adoption. Also, for both operating and finance leases, there was no impact to the accumulated deficit upon the adoption of the new standard on January 1, 2021.

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*. The guidance contains improvements to the Codification by ensuring that all guidance that requires or provides an option for an entity to provide information in the notes to condensed financial statements is codified in the Disclosure Section of the Codification. The guidance also contains Codifications that are varied in nature and may affect the application of the guidance in cases in which the original guidance may have been unclear. The Company adopted the new standard on January 1, 2021. The adoption did not have a material impact on the Company's condensed financial statements.

3. Fair Value Measurements

As of March 31, 2021, the Company held $82.1 million of investment securities, comprised of U.S. Treasury securities.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Financial instruments classified within Level 2 of the fair value hierarchy are valued based on other observable inputs. When quoted prices in active markets for identical assets or liabilities are not available, the Company relies on non-binding quotes from its investment managers, which are based on proprietary valuation models of independent pricing services. These models generally use inputs such as observable market data, quoted market prices for similar instruments, or historical pricing trends of a security relative to its peers. To validate the fair value determination provided by its investment managers, the Company reviews the pricing movement in the context of overall market trends and trading information from its investment managers. In addition, the Company assesses the inputs and methods used in determining the fair value in order to determine the classification of securities in the fair value hierarchy.

The carrying amounts of cash equivalents and investments approximate their fair value based upon quoted market prices. Certain of the Company's financial instruments are recorded at amounts that approximate their fair value, rather than at fair value on a recurring basis, due to their liquid or short-term nature, such as cash, accounts payable and accrued expenses.

The unrealized losses on short-term investments as of March 31, 2021 were insignificant. The Company does not believe that these unrealized losses are credit related but are rather a reflection of current market yields and/or current marketplace bid/ask spreads. The Company has not recognized an allowance for credit losses as of March 31, 2021.

The following tables summarize the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

		March 31, 2021			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds invested in U.S. government obligations(1)	Level 1	$ 25,213	$ —	$ —	$ 25,213
Short-term investments:					
U.S. Treasury securities	Level 2	82,038	25	—	82,063
Total		$ 107,251	$ 25	$ —	$ 107,276

(1) Included in cash and cash equivalents on the condensed balance sheet

		December 31, 2020			
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds invested in U.S. government obligations(1)	Level 1	$ 4,844	$ —	$ —	$ 4,844
Short-term and long-term investments:					
U.S. Treasury securities	Level 2	123,998	28	—	124,026
Total		$ 128,842	$ 28	$ —	$ 128,870

(1) Included in cash and cash equivalents on the condensed balance sheet

4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Laboratory and manufacturing equipment	$ 8,176	$ 8,022
Leasehold improvements	2,598	2,550
Computer and office equipment	201	201
Construction in progress	92	162
Capital leases	—	959
Total property and equipment, gross	11,067	11,894
Accumulated depreciation	(4,068)	(3,447)
Total property and equipment, net	$ 6,999	$ 8,447

Depreciation was $0.7 million and $0.2 million during the three months ended March 31, 2021 and 2020, respectively.

Capital leases consisted of laboratory and manufacturing equipment subject to capital leases. Depreciation on capital lease assets was insignificant during three months ended March 31, 2020. The accumulated depreciation on capital lease assets was $0.1 million as of December 31, 2020.

Right-of-Use Assets, Net

Right-of-use assets, net consisted of the following as of March 31, 2021 (in thousands):

	Operating Leases	Finance Leases	Total
Right-of-use assets	$ 6,013	$ 959	$ 6,972
Accumulated amortization	(563)	(163)	(726)
Right-of-use assets, net	$ 5,450	$ 796	$ 6,246

Lease expense from operating lease right-of-use assets during the three months ended March 31, 2021 was $0.6 million. Amortization expense from finance lease right-of-use assets during the three months ended March 31, 2021 was insignificant.

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Research and development expenses	$ 2,213	$ 1,303
Compensation expenses	1,037	2,389
Professional services	687	241
Other	109	115
Property and equipment	48	125
Total accrued expenses	$ 4,094	$ 4,173

Accrued research and development expenses were primarily related to clinical trials, preclinical studies, contract manufacturing and materials.

5. Leases

Operating Leases

In December 2016, the Company entered into an operating lease agreement for its principal office in South San Francisco, California. The lease term expires in August 2024. Under the lease agreement, the Company has two three-year renewal options through August 2030.

In October 2019, the Company entered into a sublease, as a lessee, for office and laboratory space located in South San Francisco, California. The sublease term expires in May 2022. Under the lease agreement, the Company has a five-year renewal option through May 2027.

In September 2020, the Company entered into a lease agreement for warehouse space in South San Francisco, California. The lease term expires in September 2021. Under the lease agreement, the Company has two six-month renewal options through September 2022.

In February 2021, the Company entered into a lease agreement for laboratory, manufacturing, warehouse and office space in South San Francisco, California. The lease term is estimated to commence in October 2021. The initial lease term is eight years from the commencement date and includes optional two five-year extensions. As of March 31, 2021, the Company does not yet have control of the underlying asset.

Finance Leases

During 2019, the Company entered into three finance lease agreements for certain laboratory equipment. Two of the leases commenced during 2019 and the third lease commenced during 2020.

The following table summarizes total lease expense during the three months ended March 31, 2021 (in thousands):

	Condensed Statements of Operations and Comprehensive Loss Classification	Three Months Ended March 31, 2021
Operating lease expense	Operating expenses	$ 597
Finance lease expense:		
Amortization of right-of-use assets	Operating expenses	48
Interest on lease liabilities	Interest income, net	9
Variable lease expense	Operating expenses	204
Short-term lease expense	Operating expenses	8
Total lease expense		$ 866

Rent expense was $0.5 million during the three months ended March 31, 2020.

The following table summarizes supplemental cash flow information during the three months ended March 31, 2021 (in thousands):

	Three Months Ended March 31, 2021
Cash paid for amounts included in measurement of liabilities:	
Operating cash flows from operating leases	$ 608
Operating cash flows from finance leases	9
Financing cash flows from finance leases	57

The following table summarizes maturities of lease liabilities and the reconciliation of lease liabilities as of March 31, 2021 (in thousands):

	Operating Leases	Finance Leases	Total
2021 (remaining nine months)	$ 1,861	$ 197	$ 2,058
2022	1,864	255	2,119
2023	1,457	171	1,628
2024	1,000	—	1,000
Total undiscounted lease liabilities	6,182	623	6,805
Less: Interest	(216)	(44)	(260)
Total discounted lease liabilities	5,966	579	6,545
Less: Lease liabilities, current	(2,377)	(235)	(2,612)
Lease liabilities, non-current	$ 3,589	$ 344	$ 3,933

The following table summarizes lease terms and discount rates as of March 31, 2021:

	Operating Leases	Finance Leases
Weighted-average remaining lease term (years)	2.9	2.3
Weighted-average discount rate	2.31%	5.95%

6. Commitments and Contingencies

Contingencies

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the three months ended March 31, 2021 and 2020, and no material legal proceedings are currently pending or threatened.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. As permitted under Delaware law and in accordance with its bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its officers and directors. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments that the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company is not currently aware of any indemnification claims. The Company also maintains director and officer insurance, which may cover certain liabilities arising from our obligation to indemnify our directors and officers. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements as of March 31, 2021 and December 31, 2020.

COVID-19

The full extent of the impact of the COVID-19 pandemic on financial markets, economies worldwide and our business is highly uncertain. As of March 31, 2021, the Company was not aware of any contingencies and no estimates were recorded on its condensed financial statements as a result of COVID-19.

7. Common Stock

As of March 31, 2021 and December 31, 2020, the Company was authorized to issue 450,000,000 shares of $0.0001 par value common stock. Common stockholders are entitled to dividends if and when declared by the Board of Directors of the Company (Board of Directors). The holder of each share of common stock is entitled to one vote. As of March 31, 2021, no dividends were declared.

Common stock reserved for future issuance, on an as converted basis, consisted of the following:

	March 31, 2021	December 31, 2020
Stock options, issued and outstanding	4,341,535	3,506,599
Stock options, authorized for future issuance	4,161,088	3,369,246
ESPP, available for future grants	665,220	314,006
Total	9,167,843	7,189,851

8. Stock-Based Compensation Expense

2020 Equity Incentive Plan

The Company's 2020 Equity Incentive Plan (the 2020 Plan) provides for the granting of incentive stock options (ISO), non-statutory stock options (NSO), restricted stock, restricted stock units, stock appreciation rights, performance units, and performance shares to employees, directors, and consultants. The Company initially reserved for issuance shares of common stock pursuant to the 2020 Plan. The shares authorized for the 2020 Plan increase annually by the lesser of (i) 3,140,062 shares, (ii) 5% of the shares of the Company's common stock outstanding on the last day of its immediately preceding fiscal year, or (iii) such other amount as determined by the Company's Board of Directors. Accordingly, effective January 1, 2021, the number of shares in the 2020 Plan increased by 1,756,068 shares, representing 5% of the prior year end's common stock outstanding. As of March 31, 2021, 4,161,088 shares of common stock remained available for future issuance under the 2020 Plan.

Options under the 2020 Plan may be granted for periods of up to 10 years and at prices no less than 100% of the estimated fair value of the underlying shares of common stock on the date of grant as determined by the Board of Directors provided that the exercise price of an ISO and NSO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant. The 2020 Plan requires that options be exercised no later than 10 years after the grant. Options granted to employees generally vest ratably on a monthly basis over four years, subject to cliff vesting restrictions.

The Company's previous 2015 Equity Incentive Plan (the 2015 Plan) and 2016 Equity Incentive Plan (the 2016 Plan) were terminated in accordance with the Company's IPO in June 2020. Shares subject to awards granted under the 2015 Plan and the 2016 Plan were added to the available shares in the 2020 Plan. Shares subject to awards granted under the 2015 Plan and 2016 Plan that are repurchased by, or forfeited to, the Company will also be reserved for issuance under the 2020 Plan.

The following summarizes stock option activity:

		Options Outstanding			
	Shares Available for Grant	Total Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	3,369,246	3,506,599	$ 6.27	8.8	$ 85,975
Additions	1,756,068	—	—		
Granted	(1,079,400)	1,079,400	53.80		
Exercised	—	(129,290)	3.07		
Cancelled	115,174	(115,174)	6.18		
Outstanding as of March 31, 2021	4,161,088	4,341,535	$ 18.19	8.5	$ 124,490
Exercisable as of March 31, 2021	—	1,182,872	$ 3.47	7.6	$ 47,950

Weighted-average grant-date fair value of the options granted during the three months ended March 31, 2021 was $34.92 per share. The intrinsic value of options exercised during the three months ended March 31, 2021 was $4.7 million.

As of March 31, 2021, the Company had $48.3 million of unrecognized stock-based compensation expense, related to options granted but not yet amortized, which will be recognized over a weighted-average period of approximately 3.0 years.

2020 Employee Stock Purchase Plan

Under the Company's 2020 Employee Stock Purchase Plan (the 2020 ESPP), employees can purchase shares of the Company's common stock each purchase period based on a percentage of their compensation, subject to certain limits. The purchase price per share is equal to the lower of 85% of the fair market value of the Company's common stock on the enrollment date or the purchase date. The 2020 ESPP offers a six-month look-back feature as well as an automatic rollover feature that provides for the offering period to be reset to a new lower-priced offering price if the market price of the stock at the purchase date is lower than the stock price at the initial enrollment date. In that case, the offering period is immediately cancelled after that purchase date, and a new two-year offering period is established using the then-current stock price as the base purchase price.

The shares authorized for the 2020 ESPP increase annually by the lesser of (i) 628,012 shares, (ii) 1% of the Company's common stock shares outstanding on the last day of its immediately preceding fiscal year, or (iii) such other amount as determined by the Company's Board of Directors. Accordingly, effective January 1, 2021, the number of shares in the 2020 ESPP increased by 351,214 shares, representing 1% of the prior year end's common stock outstanding. As of March 31, 2021, 665,220 shares of common stock remained available for future issuance under the 2020 ESPP.

The Company began recording stock-based compensation expense for its ESPP on January 1, 2021. During the three months ended March 31, 2021, the Company recorded $0.1 million stock-based compensation expense related to the ESPP. The fair value of stock-based compensation expense applicable to the ESPP was estimated using the following weighted-average assumptions:

	Three Months Ended March 31, 2021
Expected term in years	0.4
Expected volatility	52.35%
Risk-free interest rate	0.09%
Expected dividend yield	—

Stock-Based Compensation Expense

The following table summarizes the components of stock-based compensation expense recognized in the Company's condensed statements of operations and comprehensive loss during the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 1,100	$ 328
General and administrative	851	229
Total stock-based compensation expense	$ 1,951	$ 557

9. Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share (in thousands except share and per share data):

	Three Months Ended March 31,	
	2021	2020
Numerator:		
Net loss	$ (20,462)	$ (15,311)
Denominator:		
Weighted-average shares of common stock outstanding used in the calculation of basic and diluted net loss per share	35,217,773	7,417,440
Net loss per share, basic and diluted	$ (0.58)	$ (2.06)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all common stock equivalents outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	March 31,	
	2021	2020
Total stock options outstanding	4,341,535	4,043,507
Series A convertible preferred stock (as converted to common stock)	—	5,157,213
Series B convertible preferred stock (as converted to common stock)	—	3,992,919
Series C convertible preferred stock (as converted to common stock)	—	4,816,160
Total	4,341,535	18,009,799

10. Subsequent Event

On April 6, 2021, the Company completed a follow-on offering and issued total 2,875,000 shares of its common stock, including 375,000 shares of the common stock issued in connection with the full exercise by the underwriters of their options to purchase additional shares of common stock, at a price of $42.00 per share. The aggregate gross proceeds from the follow-on offering were $120.8 million. After deducting underwriting discounts and commissions of $7.2 million and deferred offering costs of $0.7 million, the net proceeds from the follow-on offering were approximately $112.9 million.

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 condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "Special Note Regarding Forward Looking Statements." Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled "Risk Factors" included elsewhere in this report.

Overview

We are a clinical-stage biopharmaceutical company leveraging our proprietary technology platform to design and develop a pipeline of novel oral biologic product candidates to treat autoimmune, inflammatory, metabolic, and other diseases. Our proprietary technology platform allows us to exploit existing natural cellular trafficking pathways to facilitate the active transport of diverse therapeutic payloads across the IE barrier. Active transport is an efficient mechanism that uses the cell's own machinery to transport materials across the IE barrier. We believe that our ability to exploit this mechanism is a key differentiator of our approach. We are developing oral biologic product candidates in patient-friendly dosage forms that are designed for either targeting local GI tissue or entering systemic circulation to precisely address the relevant biology of a disease. We are building a portfolio of oral product candidates based on our technology platform including our most advanced product candidate, AMT-101, a GI-selective oral fusion of IL-10 and our proprietary carrier molecule that has completed a Phase 1b clinical trial in patients with UC. We have initiated multiple Phase 2 clinical trials of AMT-101 in UC and related inflammatory indications. Our second product candidate, AMT-126, is a GI-selective oral fusion of IL-22 and our proprietary carrier molecule currently in development for diseases related to IE barrier function defects driven by activation of the innate immune system. We submitted a CTA for AMT-126 in December 2020 and began dosing healthy volunteers in a Phase 1a clinical trial for AMT-126 in February 2021. Our technology platform enables us to design and develop various oral biologic therapeutic modalities, such as peptides, proteins, full-length antibodies, antibody fragments, and RNA therapeutics, with potentially significant advantages over existing marketed and development-stage drugs.

Since the date of our incorporation in Delaware on November 21, 2016, we have devoted substantial resources to research and development activities, including research activities such as drug discovery, preclinical studies, and clinical trials as well as development activities such as the manufacturing of clinical and research material, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

We do not currently have any products approved for sale, and we have not generated any revenue from product sales. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development of one or more of our product candidates which we expect will take a number of years. Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of our product candidates. We expect to manage sales, marketing and distribution through internal resources and third-party relationships. While we may commit significant financial and management resources to commercial activities, we may also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities.

Manufacturing of protein therapeutics is a complex process and represents a critical path to creating oral biologic therapeutics and a key component of our long-term success. We have spent significant resources to date on developing our current manufacturing processes and know-how to produce sufficient supply and optimize functionality. We have activated a new facility located in South San Francisco where we manufacture current good manufacturing process (cGMP) drug supply. While we have successfully manufactured AMT-101 and AMT-126 cGMP drug supply at our internal facility, we may need to scale our manufacturing operations to manufacture sufficient quantity needed to advance any of our product candidates in preclinical studies and clinical trials. Accordingly, we will be required to make significant investments to expand our manufacturing facilities in the future, and our efforts to scale our internal manufacturing capabilities are subject to risks.

In addition to our in-house manufacturing facility, we expect to continue to rely on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our product candidates, as well as for our commercial products if marketing approval is obtained. By developing both internal and external cGMP manufacturing capabilities, we believe that this strategy allows us to maintain a significant degree of control over our supply chain while enabling maximum optionality for backup sources.

Since the date of our incorporation, we have incurred significant losses and negative cash flows from operations. During the quarter ended March 31, 2021, we incurred a net loss of $20.5 million and used $20.9 million of cash in operations. As of March 31, 2021, we had an accumulated deficit of $159.8 million and do not expect positive cash flows from operations in the foreseeable future. We expect to continue to incur significant and increasing losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities.

To date, we have financed our operations primarily through the private placements of convertible preferred stock and the issuance of common stock upon the completion of both our IPO and our follow-on offering. We completed our IPO in June 2020 and received net proceeds of approximately $160.6 million after deducting underwriting discounts and commissions and offering costs. We also completed our follow-on offering in April 2021 and received net proceeds of approximately $112.9 million after deducting underwriting discounts, commissions and offering costs.

We expect our expenses will increase significantly in connection with our ongoing activities, as we:

- advance product candidates through preclinical studies and clinical trials;
- pursue regulatory approval of product candidates;
- continue to invest in our technology platform;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- implement operational, financial and management information systems;
- hire additional personnel;
- buildout and expand our in-house manufacturing capabilities;
- continue to operate as a public company;
- expand our pipeline of product candidates;
- obtain, maintain, expand, and protect our intellectual property portfolio; and
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval and related commercial manufacturing build-out.

As a result, we will require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Until such time as we can generate sufficient revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. 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, and could force us to delay, reduce or eliminate our drug development or future commercialization efforts. We may also be required to grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves. The amount and timing of our future funding requirements will depend on many factors including the pace and results of our development efforts. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and investments will be sufficient to fund our planned operations through at least the next 12 months. We have based this projection on assumptions that may be inaccurate and as a result, we may utilize our capital resources sooner than we expect.

COVID-19

As a result of the COVID-19 pandemic, we have experienced disruptions to our business and could experience disruptions that severely impact our business. For example, the COVID-19 pandemic could result in delays to our clinical trials and preclinical studies for numerous reasons including difficulties in enrolling patients or healthy volunteers, diversion of healthcare resources away from the conduct of clinical trials, delays in activating clinical trial sites or receiving regulatory approvals to initiate clinical trials, and delays in receiving supplies to conduct clinical trials and preclinical studies. As of March 31, 2021, we were not aware of any contingencies and no estimates were recorded on our condensed financial statements.

Components of Results of Operations

Revenue

We have not generated any revenue from product sales or otherwise and do not expect to generate any revenue for the foreseeable future.

Operating Expenses

We classify operating expenses into two main categories: (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expenses

Our research and development expenses consist primarily of external and internal expenses incurred in connection with our research activities and development programs.

These expenses include, but are not limited to:

External expenses, consisting of:

- clinical trials—expenses associated with CROs for managing and conducting clinical trials and sample analysis;
- materials—expenses associated with laboratory supplies and other materials;
- preclinical studies—expenses associated with preclinical studies performed by vendors;
- contract manufacturing—expenses associated with manufacturing clinical trial materials including under agreements with CDMOs and other vendors; and
- other research and development—expenses associated with consulting and other external expenses.

Internal expenses, consisting of:

- personnel—personnel expenses including salaries, bonuses, benefits, and stock-based compensation expense; and
- equipment, depreciation, and facility—expenses associated with service and repair of equipment, equipment depreciation, and allocated facility costs for research and development occupied space.

To date, the vast majority of these expenses have been incurred to advance our most advanced product candidate, AMT-101. We expect that significant additional spending will be required to progress AMT-101 through the remainder of the clinical development phases. These expenses will primarily consist of expenses for the administration of clinical studies as well as manufacturing costs for clinical material supply.

In addition, we have incurred minimal expenses in connection with our second product candidate, AMT-126, including expenses for internal animal studies and preclinical studies performed at contract research organizations. We expect that significant additional spending will be required as we progress AMT-126 through clinical trials. We have also incurred minimal expenses to expand our development pipeline and for general discovery research. We expect spending for these early-stage research and development activities to increase for the foreseeable future. We deploy our personnel, equipment, and facility resources across all our research and development activities.

Research and development expenses are recognized as they are incurred. If deposits are required by external vendors, the non-current portion of the deposit is included as a prepaid expense until the related services are provided.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. We expect our research and development expenses to increase significantly in the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, as we begin to conduct larger clinical trials, as we seek regulatory approvals for any product candidates that successfully complete clinical trials, and incur expenses associated with hiring additional personnel to support our research and development efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, the successful development of our product candidates is highly uncertain, and we may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs (including salaries, bonuses, benefits, and stock-based compensation expense) for personnel in executive, finance, accounting, corporate development, and other administrative functions. General and administrative expenses also include legal fees, professional fees paid for accounting, auditing, consulting, tax, and investor relations services, insurance costs, and facility costs not otherwise included in research and development expenses, and public company expenses such as costs associated with compliance with the rules and regulations of the SEC and those of the Nasdaq Stock Market.

We expect that our general and administrative expenses will continue to increase significantly in the foreseeable future as additional administrative personnel and services are required to manage these functions of a public company and as our pipeline of product candidates expands.

Interest Income, Net and Other (Expense) Income, Net

Interest income, net and other (expense) income, net primarily consist of interest income earned on our cash, cash equivalents, investments, realized gain and loss on investments, interest expense from finance lease liabilities and capital lease obligations, and net losses on foreign currency transactions related to third-party contracts with foreign-based vendors.

Results of Operations

Comparisons of the Quarter Ended March 31, 2021 and 2020

	Quarters Ended March 31,		
	2021	2020	Change
(in thousands)			
Operating expenses:			
Research and development	$ 14,881	$ 12,954	$ 1,927
General and administrative	5,599	2,489	3,110
Total operating expenses	20,480	15,443	5,037
Loss from operations	(20,480)	(15,443)	(5,037)
Interest income, net	40	83	(43)
Other (expense) income, net	(22)	49	(71)
Net loss	$ (20,462)	$ (15,311)	$ (5,151)

Research and Development Expenses

Research and development expenses were $14.9 million during the quarter ended March 31, 2021, compared to $13.0 million during the quarter ended March 31, 2020. The overall increase in research and development expenses was primarily related to an increase in expenses associated with clinical trials, preclinical studies, compensation and facilities related expenses, offset by a decrease in materials and contract manufacturing. In particular, clinical expense increased primarily due to progressing our most advanced product candidate, AMT-101, through the completion of Phase 1 preclinical studies and initiation of Phase 2 clinical trials, and initiation of Phase 1 preclinical studies for our second product candidate, AMT-126. The following table sets forth the primary external and internal research and development expenses for the periods presented below (in thousands):

	Quarters Ended March 31,		
	2021	2020	Change
External expenses:			
Clinical trials	$ 3,130	$ 2,705	$ 425
Materials	1,456	2,730	(1,274)
Preclinical studies	909	661	248
Contract manufacturing	859	1,823	(964)
Other research and development	349	533	(184)
Internal expenses:			
Personnel	5,913	2,475	3,438
Equipment, depreciation, and facility	2,265	2,027	238
Total research and development expenses	$ 14,881	$ 12,954	$ 1,927

General and Administrative Expenses

General and administrative expenses were $5.6 million during the quarter ended March 31, 2021, compared to $2.5 million during the quarter ended March 31, 2020. The overall increase in general and administrative expenses was primarily related to an increase of $1.9 million in personnel and administrative costs due to an increase in headcount and an increase of $1.1 million in professional fees.

Interest Income, Net

Interest income, net was minimal during each of the quarters ended March 31, 2021 and March 31, 2020.

Other (Expense) Income, Net

Other (expense) income, net was minimal during each of the quarters ended March 31, 2021 and March 31, 2020.

Liquidity and Capital Resources

We believe that our existing cash, cash equivalents, and investments as of March 31, 2021 will be sufficient to fund our current operating plan through at least the next 12 months.

Since the date of our incorporation, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We anticipate that we will continue to incur net losses for the foreseeable future. Our operations have been financed primarily by net proceeds from sales of our convertible preferred stock and common stock through both our IPO in June 2020 and our follow-on offering in April 2021. As of March 31, 2021, we had an accumulated deficit of $159.8 million. As of March 31, 2021, we had cash, cash equivalents and investments of $108.3 million.

Future Funding Requirements

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval and commercialize any of our product candidates, and we do not know when, or if at all, that will occur. We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. Our primary uses of cash are to fund our operations, which consist primarily of research and development expenses related to our programs, and to a lesser extent, general and administrative expenses. We expect our expenses to continue to increase in connection with our ongoing activities as we continue to advance our product candidates. In addition, we expect to incur additional costs associated with operating as a public company.

We may seek to raise capital through public equity or debt financings, collaborative agreements or other arrangements with other companies, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the progress, costs, trial design, results of and timing of our various clinical trials of AMT-101 and preclinical studies and clinical trials of AMT-126;
- the progress, costs and results of our research pipeline;
- the willingness of the FDA, EMA, or other regulatory authorities to accept our product candidates, as well as data from our completed and planned clinical trials and preclinical studies and other work, as the basis for review and approval of our product candidates for various indications;
- the outcome, costs and timing of seeking and obtaining FDA, EMA, and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue;
- our ability to manufacture sufficient quantities of our drug candidates;
- our need to expand our research and development activities;
- the costs associated with manufacturing our product candidates, including building-out and expanding our own manufacturing facilities, and establishing commercial supplies and sales, marketing, and distribution capabilities;
- the costs associated with securing and establishing commercialization;
- the costs of acquiring, licensing, or investing in businesses, drug candidates, and technologies;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights;
- our need and ability to retain key management and hire scientific, technical, business, and medical personnel;
- the effect of competing drugs and drug candidates and other market developments;
- the timing, receipt, and amount of sales from our potential products;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing of and success of any collaboration, licensing or other arrangements which we may enter in the future; and
- the potential effects of the COVID-19 pandemic on our business operations.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. If we raise additional capital through debt financing, we may be subject to covenants that restrict our operations including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others the rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. In addition, our ability to raise additional capital may be adversely impacted if there is a downturn in global economic conditions.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash, cash equivalents, and restricted cash for the periods presented below (in thousands):

	Quarters Ended March 31,	
	2021	2020
Net cash used in operating activities	$ (20,948)	$ (13,711)
Net cash provided by investing activities	41,921	8,608
Net cash provided by (used in) financing activities	303	(1,657)
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 21,276	$ (6,760)

Cash Used in Operating Activities

Net cash used in operating activities during the quarter ended March 31, 2021 was $20.9 million, which consisted of a net loss of $20.5 million and net decrease of $3.7 million in our net operating assets and liabilities, offset by $3.3 million in non-cash charges. The net decrease in our operating assets and liabilities was primarily due to decreases of $1.7 million in accounts payable and accrued expenses, a decrease of $1.3 million in prepaid expenses, a decrease of $0.6 million in lease liabilities, operating lease and a decrease of $0.1 million in other current assets. The non-cash charges primarily consisted of stock-based compensation expense of $2.0 million, depreciation and amortization expenses of $0.7 million and non-cash lease expense of $0.6 million.

Net cash used in operating activities during the quarter ended March 31, 2020 was $13.7 million, which consisted of a net loss of $15.3 million, offset by a net increase of $0.8 million in our net operating assets and liabilities and $0.8 million in non-cash charges. The net increase in our operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of $3.2 million and an increase in other assets of $0.5 million, partially offset by a decrease of $2.9 million in prepaid expenses and other current assets. The non-cash charges primarily consisted of stock-based compensation expense of $0.6 million and depreciation expense of $0.2 million.

Cash Used in Investing Activities

Cash provided by investing activities during the quarter ended March 31, 2021 was $41.9 million, consisting primarily of sales and maturities of investments of $42.0 million, offset by purchase of property and equipment of $0.1 million.

Cash provided by investing activities during the quarter ended March 31, 2020 was $8.6 million, consisting primarily of sales and maturities of investments of $18.1 million, offset by purchase of investments of $8.3 million and purchase of property and equipment of $1.2 million.

Cash Provided by Financing Activities

Cash provided by financing activities during the quarter ended March 31, 2021 was $0.3 million, consisting primarily of net proceeds received from the stock option exercises of $0.4 million, offset by principal payments for the finance lease of $0.1 million.

Cash used in financing activities during the quarter ended March 31, 2020 was $1.7 million, consisting primarily of payments for issuance costs related to the initial public offering of $1.7 million.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of March 31, 2021 (in thousands):

	Payments Due by Period			
	Up to December 31, 2021	Up to December 31, 2023	Up to December 31, 2025	Total
Operating lease commitments (1)	$ 1,861	$ 3,321	$ 1,000	$ 6,182
Finance lease commitments (2)	197	426	—	623
Total	$ 2,058	$ 3,747	$ 1,000	$ 6,805

(1) Payments due for our headquarters, manufacturing facility and warehouse
(2) Payments due for certain laboratory equipment

Off-Balance Sheet Arrangements

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

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

The economic uncertainty in the current environment caused by the COVID-19 pandemic could limit our ability to accurately make and evaluate our estimates and judgments. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

While our significant accounting policies are described in the notes to our financial statements, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

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 filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on March 19, 2021 and the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the quarter ended March 31, 2021, except as described in Note 2 to the unaudited interim condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K filed on March 19, 2021.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. As of March 31, 2021, we had cash, cash equivalents, and investments of $108.3 million, consisting of U.S. Treasury securities and interest-bearing money market accounts for which the fair market value would be affected by changes in the general level of U.S. interest rates. However, due to the short-term maturities and the low-risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our cash, cash equivalents, and investments. We do not believe that inflation, interest rate changes, or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

The Company was not exposed to material foreign currency risk during the quarter ended March 31, 2021.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, 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 (the Exchange Act)). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our 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

Investing in our 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." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, growth prospects or stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risk Factors Summary

Investing in shares of our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. The principal factors and uncertainties that make investing in shares of our common stock risky include, among others:

- We are early in our development efforts, have a limited operating history, and no products approved for commercial sale;
- We have incurred significant net losses in each period since inception, and we expect to continue to incur net losses for the foreseeable future;
- We will need to obtain substantial additional capital to finance our operations;
- We may not be successful in our efforts to use and expand our technology platform to build a pipeline of oral biologic product candidates;
- COVID-19 or other future pandemics could adversely impact our business, including our ongoing and planned clinical trials and preclinical studies;
- Research and development related to novel biological therapeutics is inherently risky and our business is heavily dependent on the successful development of our product candidates, which are in preclinical and the early stages of clinical development;
- Our clinical trials may fail to demonstrate evidence of the safety and efficacy of our product candidates which would prevent, delay, or limit the scope of regulatory approval and commercialization;
- We may be unable to obtain U.S. or foreign regulatory approval for our product candidates and, as a result, may be unable to commercialize our product candidates;
- Our success depends on our ability to protect our intellectual property as well as operate without infringing on the rights of third parties;
- We are highly dependent on our key personnel and if we are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be able to successfully implement our business strategy; and
- We have previously identified material weaknesses in our internal control over financial reporting and if we are unable to maintain effective internal controls or if we identify additional material weaknesses in the future, we may not be able to accurately or timely report our financial condition or results of operations.

Risks Related to Our Business, Financial Condition, and Capital Requirements

We are early in our development efforts, have a limited operating history and have no products approved for commercial sale, which makes it difficult to evaluate our current business and predict our future success and viability.

We are an early clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects.

We have no products approved for commercial sale and have not generated any revenue from product sales. We are developing a novel technology platform which is an unproven and highly uncertain undertaking and involves a substantial degree of risk. While we have begun Phase 2 clinical trials for our most advanced product candidate, AMT-101, a GI-selective oral fusion of IL-10, and have initiated a Phase 1 clinical trial of AMT-126 in February 2021, we have not initiated clinical trials for any of our other product

candidates. To date, we have not obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third-party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty.

We will encounter expenses, difficulties, complications, delays, and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses in each period since inception, and we expect to continue to incur net losses for the foreseeable future.

We have incurred net losses in each reporting period since our inception, including net losses of $20.5 million and $15.3 million during the quarters ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $159.8 million.

We have invested significant financial resources in research and development activities, including for our preclinical and clinical product candidates. We have not generated any revenue from product sales to date and we do not expect to generate revenue from product sales for several years, if at all. The amount of our future net losses will depend, in part, on the level of our future expenditures and revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We expect to continue to incur significant expenses and increasingly higher operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our research and discovery activities;
- continue the development of our proprietary technology platform;
- progress our current and any future product candidates through preclinical and clinical development;
- initiate and conduct additional preclinical, clinical, or other studies for our product candidates;
- work with our CDMOs to manufacture our product candidates for our clinical trials;
- continue to establish and operate a manufacturing facility;
- change or add additional contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates;
- establish sales, marketing, and distribution infrastructure to commercialize any products for which we obtain approval;
- take steps to seek protection of our intellectual property and defend our intellectual property against challenges from third parties;
- obtain, expand, maintain, protect, and enforce our intellectual property portfolio;
- pursue any licensing or collaboration opportunities;
- attract, hire, and retain qualified personnel including clinical, scientific, management, and administrative personnel;
- provide additional internal infrastructure to support our continued research and development operations and any planned commercialization efforts in the future;
- experience any delays or encounter other issues related to our operations;
- implement operations, financial, and management information systems;
- meet the requirements and demands of being a public company; and
- defend against any product liability claims or other lawsuits related to our products or operations.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity, working capital, and our ability to fund our development efforts and achieve and maintain profitability. 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.

We have historically financed our operations primarily through private placements of our convertible preferred stock and the sale of common stock in public equity issuances, such as our IPO in June 2020 and our follow-on equity offering in April 2021. We may seek to raise capital through debt financings, private or public convertible debt financings, private or public equity financings, license agreements, collaborative agreements or other arrangements with other companies, or other sources of financing. There can be no assurance that such financing will be available or will be at terms acceptable to us. If adequate funds are not available, we may be required to reduce operating expenses, delay or reduce the scope of our development efforts, obtain funds through arrangements with others that may require us to relinquish rights to certain of our technologies or products that we would otherwise seek to develop or commercialize ourselves, or cease operations.

Developing biologic therapeutics is a highly uncertain undertaking and involves a substantial degree of risk.

We have no products approved for commercial sale. To obtain revenue from the sales of our products that are significant or large enough to achieve profitability, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing, and marketing approved products with significant commercial success. Our ability to generate revenue and achieve profitability depends on many factors, including:

- initiating, enrolling patients in and completing clinical trials of product candidates on a timely basis;
- completing research and preclinical and clinical development of our product candidates;
- obtaining specialty raw materials for use in production of our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development and clinical trials;
- satisfying any post-marketing approval commitments required by applicable regulatory authorities;
- developing a sustainable, consistent, time-sensitive, and scalable manufacturing process for our product candidates, either by ourselves or with third-party manufacturers, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and commercial demand of our products;
- identifying, assessing, acquiring, and/or developing new product candidates or technologies;
- launching and successfully commercializing products for which we have obtained regulatory and marketing approval by establishing a sales, marketing, and distribution infrastructure;
- obtaining and maintaining an adequate price for our products, both in the United States and in foreign countries where our products are commercialized;
- obtaining coverage and adequate reimbursement for our products from payors and patients' willingness to pay in the absence of such coverage and adequate reimbursement;
- obtaining market, patient, and medical community acceptance of our products as viable treatment options;
- addressing any competing technological and market developments;
- obtaining additional funding to develop, and potentially manufacture and commercialize our product candidates;
- maintaining, protecting, expanding, and enforcing our portfolio of intellectual property rights, including patents, trade secrets, and know-how;
- attracting, hiring, and retaining qualified personnel; and
- negotiating favorable terms in any collaboration, licensing, or other arrangements which we may pursue.

Because of the numerous risks and uncertainties associated with developing biologic therapeutics, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or foreign regulatory authorities, to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we

anticipate incurring significant costs associated with launching and commercializing any approved product candidate and ongoing compliance efforts.

We will need to obtain substantial additional capital to finance our operations. A failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate our research and drug development programs, future commercialization efforts, product development, or other operations.

Developing biologic therapeutics, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. Our operations have required substantial amounts of cash since inception, and we expect our expenses to increase significantly in the foreseeable future. To date, we have financed our operations primarily through the sale of equity securities. Developing our product candidates and conducting clinical trials for the treatment of autoimmune, inflammatory, metabolic, and other diseases will require substantial amounts of capital. We will also require a significant amount of capital to commercialize any approved products. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Furthermore, other unanticipated costs may also arise.

As of March 31, 2021, we had cash, cash equivalents, and investments of $108.3 million. In April 2021, we also issued common stock in a follow-on public offering which resulted in net proceeds of $112.9 million after deducting the underwriting discounts and commissions and offering expenses. Based on our current operating plan, we believe that our existing cash, cash equivalents, and investments will be sufficient to fund our projected operations at least 12 months after the date of issuance of the condensed financial statements. Our estimate as to how long we expect our existing cash, cash equivalents, and investments to be available to fund our operations is based on assumptions that may prove inaccurate, and we could use our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate.

We will require additional capital for the further development and, if approved, commercialization of our product candidates. Our future funding requirements will depend on many factors, including but not limited to:

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

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include the issuance of warrants or

covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise funds through collaborations, strategic alliances, or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, or grant licenses on terms that may not be favorable to us. 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.

Additional capital may not be available when we need it, on terms acceptable to us or at all. We have no committed source of additional capital. If adequate capital is not available to us on a timely basis or on acceptable terms, we may be required to significantly delay, scale back, or discontinue our research and development programs or the commercialization of any product candidates, if approved, or be unable to continue or expand our operations, or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition, results of operations, and growth prospects, and cause the price of our common stock to decline.

We may not be successful in our efforts to use and expand our proprietary technology platform to build a pipeline of oral biologic product candidates.

A key element of our strategy is to leverage our technology platform to expand our pipeline of oral biologic product candidates and in order to do so, we must continue to invest in our platform and development capabilities. Although our research and development efforts to date have resulted in a pipeline of product candidates, these product candidates may not be safe and effective. In addition, although we expect that our platform will allow us to develop a diverse pipeline of product candidates across multiple therapeutic areas and modalities, we may not prove to be successful at doing so. Furthermore, we may also find that the uses of our platform are limited because alternative uses of our biologic therapeutics prove not to be safe or effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance. Even after approval, if we cannot successfully develop or commercialize our products, or if serious adverse events are discovered after commercialization, we will not be able to generate any product revenue, which would adversely affect business.

We have limited resources and are currently focusing our efforts on developing AMT-101 and AMT-126 for particular indications and advancing our preclinical studies and clinical trials. As a result, we may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable.

We currently are focused on developing our most advanced product candidates: AMT-101 and AMT-126. Our goal is to expand the therapeutic and commercial potential of our targets and product candidates to additional indications to maximize value and increase our probability of success. However, due to the significant resources required for the development of our product candidates, we must focus on specific product candidates and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management, and financial resources toward particular product candidates or indications may not lead to the development of any viable commercial product and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in immunology and inflammation, gastroenterology, and metabolic diseases, or the biopharmaceutical industry as a whole, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to maximize profitability on our product candidates, capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.

We currently rely and expect to continue to rely on third parties, such as contract research organizations (CROs), contract development and manufacturing organizations (CDMOs), medical institutions, academic institutions, and clinical investigators to conduct some aspects of our research and preclinical studies and our clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations for any reason including the COVID-19 pandemic. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with current good clinical practices (cGCP) for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible, reproducible, and accurate and that the rights, integrity, and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

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

The manufacturing of our product candidates is complex. We and our third-party manufacturers may encounter difficulties in production. If we encounter any such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale, could be delayed or halted entirely.

Manufacturing of biologic therapeutics is a complex process and represents a critical path to creating oral biologic product candidates and a key component of our long-term success. We have spent significant resources and plan to continue to spend significant resources to develop our current manufacturing processes and know-how to produce sufficient supply and optimize functionality. While we have activated a new facility located in South San Francisco that will be our primary manufacturing site of drug substance or bulk drug intermediate, opening a new facility is time intensive and costly and we may experience difficulties associated with the transition to this new facility, including as a result of the COVID-19 pandemic. Although we have successfully manufactured AMT-101 and AMT-126 clinical drug supply at our internal facility, we will need to scale our manufacturing operations. We will also continue to rely on third-party manufacturers to execute certain steps in the manufacturing of our product candidates. Accordingly, we will be required to make significant investments to expand our manufacturing facilities in the future, and our efforts to scale our internal manufacturing capabilities may not succeed.

The process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. We have experienced in the past situations in which our contract manufacturer has failed to successfully complete a scheduled manufacturing run as a result of their manufacturing process errors. We also have experienced in the past situations in which we failed to successfully complete a schedule manufacturing run at our primary manufacturing site. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Furthermore, it is too early to estimate our cost of goods sold. The actual cost to manufacture our product candidates could be greater than we expect because we are early in our development efforts and our platform is based on a novel therapeutic approach. Failure to develop our own manufacturing capacity may hamper our ability to further process improvement, maintain quality control, limit our reliance on contract manufacturers, and protect our trade secrets and other intellectual property.

We currently rely on third-party manufacturers to produce our product candidates. Any failure by a third-party manufacturer to produce acceptable product candidates for us pursuant to our specifications and regulatory standards may delay or impair our ability to initiate or complete our clinical trials, obtain and maintain regulatory approvals or commercialize approved products.

Although we have successfully manufactured AMT-101 and AMT-126 clinical drug supply at our internal facility, we currently have limited in-house manufacturing experience and personnel. While we have implemented in-house manufacturing that we expect will be

our primary site for the manufacture of clinical trial product candidates, we do not currently have the infrastructure or internal capability to manufacture our product candidates for commercialization purposes. We expect to continue to rely on third parties for certain manufacturing operations of our product candidates for preclinical studies and clinical trials, in compliance with applicable regulatory and quality standards, including cGMP, and may do so for the commercial manufacture of some of our product candidates, if approved. If we are unable to arrange for and maintain third-party manufacturing sources that are capable of meeting regulatory standards, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. 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, the COVID-19 pandemic, or otherwise, we could experience delays, disruptions, suspensions, or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. Such failure or substantial delay or loss of supply could materially harm our business.

Reliance on third-party manufacturers entails risks to which we may not be subject if we manufactured product candidates ourselves, including:

- the possible 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;
- reliance on the third-party for regulatory compliance and quality control and assurance and failure of the third-party to comply with regulatory requirements;
- the possibility of breach of the manufacturing agreement by the third-party because of factors beyond our control (including a failure to manufacture our product candidates in accordance with our product specifications);
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- the possibility of 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;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possibility of termination or nonrenewal of the agreement by the third-party at a time that is costly or damaging to us.

In addition, the FDA, European Medicines Agency (EMA), and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state, and other foreign authorities. 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. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in sanctions being imposed on us, including fines, injunctions, civil penalties, restrictions on the product or on the manufacturing or laboratory facility, including license revocation, marketed product recall, suspension of manufacturing, product seizure, voluntary withdrawal of the product from the market, operating restrictions, or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations.

We may have little to no control regarding the occurrence of third-party manufacturer incidents. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, would lead to a delay in, or failure to seek or obtain, regulatory approval of any of our product candidates. Furthermore, any change in manufacturer of our product candidates or approved products, if any, would require new regulatory approvals, which could delay completion of clinical trials or disrupt commercial supply of approved products.

Our current and anticipated future dependence upon others for the manufacture 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.

In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer, we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to change manufacturers for

any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on third-party suppliers for the supply of the raw materials required for the production of our product candidates, and we expect to some extent continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including delays as a result of COVID-19, limited control over pricing, availability, quality, and delivery schedules and non-exclusivity. As a small company, our negotiating leverage is limited, and we are likely to get lower priority than our competitors who are larger than we are. We do not have long-term supply agreements, and we purchase our required supplies on a development manufacturing services agreement or purchase order basis. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require to satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of March 31, 2021, we had 90 full-time employees. As our development plans and strategies develop, we must add a significant number of additional managerial, operational, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical development and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties;
- expanding our operational, financial and management controls, reporting systems, and procedures; and
- managing increasing operational and managerial complexity.

Our future financial performance and our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage 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. There can be no assurance that the services of these 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 consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

The COVID-19 pandemic could adversely impact our business including our ongoing and planned clinical trials and preclinical studies.

Since the COVID-19 virus was reported in December 2019 in Wuhan, China, the virus has spread extensively throughout the world, resulting in the World Health Organization characterizing COVID-19 as a pandemic. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, such as the duration of the outbreak, 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 and to address its impact, including on financial markets or otherwise. While we have been able to mitigate the impact of the COVID-19 pandemic on our business to date, we could experience future disruptions that could severely impact our business, current and planned clinical trials and preclinical studies, including:

- delays or difficulties in enrolling and retaining participants, particularly subjects who are at a higher risk of severe illness or death from COVID-19, in our Phase 2 clinical trials with AMT-101 and our other future clinical trials or those conducted by third parties and further incurrence of additional costs as a result of any clinical trial delays and adjustments;
- challenges related to ongoing and increased operational expenses related to the COVID-19 pandemic;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- difficulties interpreting data from our clinical trials due to the possible effects of COVID-19 on patients;
- 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 clinical trials;
- interruption of key clinical trial activities, such as clinical trial site 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 trial procedures, which may impact the integrity of subject data and clinical trial endpoints;
- limitations in resources, including our employees, that would otherwise be focused on the conduct of our business or our current or planned clinical trials or preclinical studies, including because of sickness, the desire to avoid contact with large groups of people or restrictions on movement or access to our facility as a result of government-imposed “shelter in place” or similar working restrictions;
- interruptions, difficulties or delays arising in our existing operations and company culture as a result of some of our employees working remotely, including those hired during the COVID-19 pandemic;
- increased cybersecurity risks resulting from some of our employees working remotely;
- delays in receiving approval from regulatory authorities to initiate our clinical trials;
- interruptions in preclinical studies due to restricted or limited operations at CROs conducting such studies;
- interruptions or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States;
- delays in receiving the supplies, materials and services needed to conduct clinical trials and preclinical studies;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs or require us to discontinue clinical trials altogether;
- interruptions or delays to our pipeline and research programs, and incurrence of additional costs as a result of any delays or adjustments; and
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or furlough of government or contractor personnel.

Further, as a result of the COVID-19 pandemic, the extent and length of which is uncertain, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect trial participants from the COVID-19 virus, which may include using telemedicine visits, remote monitoring of patients and clinical sites, and measures to ensure that data from clinical trials that may be disrupted as a result of the pandemic are collected pursuant to the trial protocol and consistent with cGCP, with any material protocol deviation reviewed and approved by the site Institutional Review Board (IRB). Patients who may miss scheduled appointments, any interruption in trial drug supply, or other consequence that may result in incomplete data being generated during a trial as a result of the pandemic must be adequately documented and justified. For example, the FDA issued guidance on March 18, 2020, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describe a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report (or as a separate document) contingency measures implemented to manage the trial, and any disruption of the trial as a result of the COVID-19 pandemic; a list of all trial participants affected by the COVID-19-pandemic related trial disruption by unique subject identifier and by investigational site, and a description of how the individual’s participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or trial, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy

results reported for the trial. In June 2020, the FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs. Additional COVID-19 related guidance recently released by FDA include guidance addressing resuming normal drug and biologics manufacturing operations; manufacturing, supply chain, and inspections; and statistical considerations for clinical trials during the COVID-19 public health emergency.

While the extent of the impact of the COVID-19 pandemic and current and future regulatory policies and requirements on our business and financial results are uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition, and operating results.

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

Risks Related to the Discovery, Development, and Commercialization of Our Product Candidates

Research and development related to novel biologic therapeutics is inherently risky. Our business is heavily dependent on the successful development of our product candidates, which are in preclinical and the early stages of clinical development. We cannot give any assurance that any of our product candidates will receive regulatory or marketing approval, which is necessary before they can be commercialized.

Our oral biologic product candidates’ use of active transport to translocate through the IE barrier is a novel therapeutic approach. Our active transport approach differs from current oral biologics and peptides and is unproven. We are at the early stages of development of our product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or clinical trials;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- the product candidates that we develop may not be sufficiently covered by intellectual property for which we hold exclusive rights;
- the product candidates that we develop may be covered by third parties’ patents or other intellectual property or exclusive rights;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in development and commercial quantities at an acceptable cost, or at all;
- the product candidates that we develop may be novel and therefore, not accepted by the medical community;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate, to gain market acceptance; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for one or more product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We may not be successful in our efforts to further develop our current product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates are in the early stages of development and will require significant additional clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all.

We have never completed a clinical development program. We currently have two product candidates, AMT-101 and AMT-126. None of our product candidates have advanced into late-stage development and it may be years before any such trial is initiated, if at all. Further, we cannot be certain that any of our product candidates will be successful in clinical trials. We may in the future advance product candidates into clinical trials and terminate such trials prior to their completion.

If any of our product candidates successfully complete clinical trials, we generally plan to seek regulatory approval to market our product candidates in the United States, the European Union, and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or applied for regulatory approval to market any product candidate. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would adversely affect our viability. To obtain regulatory approval in countries outside of the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, manufacturing and controls, clinical trials, commercial sales, pricing, and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our business, financial condition, results of operations, and our growth prospects could be negatively affected.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

Investment in biopharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates.

We may encounter delays in our preclinical studies or clinical trials, or may not be able to conduct or complete our preclinical studies or clinical trials on the timelines we expect, if at all.

Preclinical studies and clinical testing are expensive, time consuming, and subject to uncertainty. We cannot guarantee that any preclinical studies and clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an IND application or a CTA will result in the FDA, EMA, or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these studies or trials begin, issues may arise that could suspend or terminate such preclinical studies or clinical trials. A failure of one or more preclinical studies or clinical trials can occur at any stage of testing, and our future preclinical studies or clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of preclinical studies or clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in confirming target engagement, biomarkers, patient selection, or other relevant criteria to be utilized in preclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting, and training suitable clinical investigators;
- delays in obtaining required IRB approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including:
- after review of an IND or amendment, CTA or amendment, or equivalent application or amendment;
- as a result of a new safety finding that presents unreasonable risk to clinical trial participants;
- a negative finding from an inspection of our clinical trial operations or trial sites; or
- the finding that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in identifying, recruiting, and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials, or failing to return for post-treatment follow-up;

- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's or any other regulatory authority's cGCP requirements, or applicable EMA or other regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- health epidemics such as the COVID-19 pandemic;
- preclinical studies or clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in preclinical studies or clinical trials or the inability to do any of the foregoing.

Any inability to successfully initiate or complete preclinical studies or clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required, or we may elect, to conduct additional studies to bridge our modified product candidates to earlier versions. Preclinical studies or clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a preclinical study or clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA, or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial 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, EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial.

We may in the future terminate our clinical trials prior to their completion, which could adversely affect our business.

Delays in the completion of any preclinical study or clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay, or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

If we do not achieve our projected development goals in the timeframes we announce and expect, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline.

We may encounter difficulties enrolling patients or healthy volunteers in our clinical trials, and our clinical development activities could thereby be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the patient eligibility criteria defined in the protocol;
- the size of the trial population required for analysis of the trial's primary endpoints;
- the proximity of patients to a trial site;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- our ability to obtain and maintain patient consents;
- health epidemics such as the COVID-19 pandemic; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason.

In addition, the size and nature of the patient populations of the indications for which we are targeting may present difficulties or delays in enrollment due to factors such as being orphan disease populations or competition for patients with other trials. For example, we are aware of multiple clinical trials in UC being conducted by competitors which may make it difficult for us to enroll sufficient patients.

Our preclinical studies and clinical trials may fail to demonstrate evidence of the safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex, and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Preclinical studies and clinical testing are expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical studies or clinical trial process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including variability in the purity or potency of different batches of the same product candidate, changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen, and other aspects of the clinical trial protocols and the rate of dropout among clinical trial participants. Open-label extension studies may also extend the timing and cost of a clinical test substantially. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our current clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition, and results of operations.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidates, which may also limit its commercial potential.

We face significant competition and if our competitors develop and market technologies or products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The development and commercialization of biologic therapeutics is highly competitive and subject to rapid and significant technological change. We are currently developing biologic therapeutics that will compete with other drugs and therapies that currently exist or are being developed in the segments of the pharmaceutical, biotechnology, and other related markets that develop treatments for autoimmune, inflammatory, metabolic, and other diseases. The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. Any product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for the research, development, manufacturing, and commercialization of therapies aimed at treating autoimmune, inflammatory, metabolic, and other diseases. Many of our competitors have significantly greater financial, manufacturing, marketing, technical and human resources and commercial expertise than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing biologic therapeutics. These companies also have significantly greater research and marketing capabilities than we do. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection or FDA or other regulatory approval or discovering, developing and commercializing products in our field before we do.

In particular, with respect to our most advanced product candidates, AMT-101 and AMT-126, we compete against companies that produce injectable biologic therapeutics such as AbbVie Inc., Eli Lilly and Co., Janssen Pharmaceuticals, Inc., Roche Holding Ltd., and Takeda Pharmaceutical Company Ltd., as well as companies that produce oral products such as Abivax SA, Arena Pharmaceuticals, Inc., Bristol-Myers Squibb Co., Galapagos NV, Gilead Sciences, Inc., Gossamer Bio, Inc., Landos Biopharma, Inc., Pfizer Inc., Protagonist Therapeutics, Inc., and Theravance Biopharma, Inc.

We are not aware of any other company or organization that has developed an FDA-approved oral biologic, other than peptides. However, we are aware of other companies developing oral biologic drug candidates using their own technology platform.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient or are less expensive than the products that we may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

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. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA, EMA, or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan drug exclusivity from the FDA for indications our product candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any products we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity, and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate, or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Our product candidates may face competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our product candidates may face competition from biosimilar products or alternative therapies. In the United States, our product candidates are regulated by the FDA as biologic products and we intend to seek approval for these product candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

We believe that any of our product candidates approved as a biologic 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. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product but will not be able to get it on the market until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

Even if any product candidates we develop receive marketing approval, our product candidates may not achieve adequate market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials and published in peer-review journals or presented at medical conferences;

- the potential and perceived advantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- sufficient third-party coverage or adequate reimbursement and patients' willingness to pay in the absence of such coverage and adequate reimbursement;
- the ability to offer appropriate patient access programs, such as co-pay assistance;
- the extent to which physicians recommend our products to their patients;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by FDA, EMA, or other regulatory authorities;
- product labeling or product insert requirements of the FDA, EMA, or other comparable foreign regulatory authorities, including any limitations, contraindications, or warnings contained in a product's approved labeling;
- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength and effectiveness of sales and marketing and distribution efforts; and
- the prevalence and severity of any side effects.

If any product candidates we develop do not achieve an adequate level of acceptance, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing, or distribution of biologic therapeutics. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities for some of our product candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future approved products;
- our inability to obtain coverage and adequate reimbursement for our products from payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

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

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

Our projections of both the number of people who have the diseases we may be targeting, as well as the subset of people with these health issues who have the potential to benefit from treatment with our technology platform and investigational medicines, and any product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases and health issues. The potentially addressable patient population for our investigational medicines may be limited or may not be amenable to treatment with our technology platform or investigational medicines. Even if we obtain significant market share for our products, if approved, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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

The time required to obtain approval by the FDA, EMA, and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity, and novelty of the product candidates involved. 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, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other studies. We have not submitted for, or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval in an initial or subsequent indication for many reasons, including but not limited to the following:

- the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design, implementation, or results of our clinical trials;
- the FDA, EMA, or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities, or other characteristics that preclude our further development of our product candidates or our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we may be unable to demonstrate to the FDA, EMA, or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio when compared to the standard of care is acceptable;
- the FDA, EMA, or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application (NDA), BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA, or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for a proposed indication is acceptable;

- the FDA, EMA, 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, EMA, 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 any of our product candidates, which would significantly harm our business, results of operations, and prospects.

The FDA has limited experience with our technology platform and we are not aware of any similar technology platform which has been approved by the FDA, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. For example, since the scientific evidence to support the feasibility of developing our product candidates and discovery programs is both preliminary and limited, the FDA may require us to provide additional data to support our regulatory applications. Moreover, advancing our novel oral biologic product candidates creates other significant challenges for us, including educating medical personnel regarding a novel technology platform and its potential efficacy and safety benefits.

Further, the ability of the FDA or other regulatory agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, government shutdowns including as a result of the COVID-19 pandemic, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may be subject to post-marketing testing requirements to maintain regulatory approval. In addition, upon obtaining any marketing approvals, we may have difficulty in establishing the necessary sales and marketing capabilities to gain market acceptance.

If any of our product candidates prove to be ineffective, unsafe or commercially unviable, our entire pipeline could have little, if any, value, and it may prove to be difficult or impossible to finance the further development of our pipeline. Any of these events would have a material and adverse effect on our business, financial condition, results of operations, and prospects.

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

Adverse events or other 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, EMA, or other comparable foreign regulatory authorities. AMT-101 is a GI-selective oral fusion of IL-10, and previous clinical trials conducted in the field with systemic IL-10 showed significant toxicities that prevented further development.

Side effects could affect patient recruitment, the ability of enrolled patients to complete the trial, and/or result in potential product liability claims. We are required to maintain product liability insurance pursuant to certain of our development and commercialization agreements. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could adversely affect our results of operations, business, and reputation. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates, and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product and cause us to recall our products;
- regulatory authorities may require additional warnings on the label;

- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a risk evaluation and mitigation strategy plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements, such as boxed warning on the packaging, to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations, and growth prospects.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk when and if we commercialize any products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale post-approval. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. Claims could also be asserted under state consumer protection laws. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing, or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize any products.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

If we succeed in developing any products, we intend to market them in the United States as well as the European Union and other foreign jurisdictions. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements.

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, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the

manufacturing, marketing, and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical 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 products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with 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.

Coverage and reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If reimbursement is not available or is not sufficient for our products, it is less likely that our products will be widely used.

Even if our product candidates are approved for sale by the appropriate regulatory authorities, market acceptance and sales of these products will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Third-party payors, such as government healthcare programs, private health insurers and health maintenance organizations, decide what therapies they will cover and establish the level of reimbursement for such therapies. We cannot be certain that coverage and reimbursement will be available or adequate for any products that we develop. If coverage and adequate reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our product candidates, if approved.

There may be significant delays in obtaining coverage and reimbursement for newly approved therapies, and coverage may be more limited than the purposes for which the therapy is approved by the FDA, EMA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a therapy will be paid for in all cases or at a rate that is commensurate with our product pricing that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new therapies, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the therapy and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost therapies and may be incorporated into existing payments for other services. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Net prices for therapies may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future change to laws that presently restrict imports of therapies from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement from third-party payors, including both government-funded and private payors, for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We may in the future conduct clinical trials for our product candidates outside the United States and the FDA, EMA, and applicable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more of our clinical trials outside the United States. For example, we have enrolled patients outside the United States in our Phase 2 clinical trials of AMT-101. The acceptance of trial data from clinical trials conducted outside the United States by the FDA, EMA, or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to cGCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA, or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States. If the FDA, EMA, or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to extensive regulatory scrutiny.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety,

efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, EMA, and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, BLA, or marketing authorization application (MAA). Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a risk evaluation and mitigation strategy), or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA, and comparable foreign regulatory authorities. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to biologic therapeutics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval, commonly referred to as "off-label uses." The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer communications on the subject of off-label use of their products. The holder of an approved NDA, BLA, or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing trial or failure to complete such a trial could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain products; or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We may seek orphan drug designation for one or more of our product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

In the future, we may seek orphan drug designations for one or more of our product candidates, but may be unable to obtain an orphan drug designation for any additional product candidates. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. 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 user-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. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other NDA or BLA applications to market the same drug or biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

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

In the future, we may seek a breakthrough therapy designation for one or more of our investigational medicines. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the biologics license application.

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

We may seek Fast Track designation for some of our investigational medicines. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular investigational medicine is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. If our clinical development program does not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended, or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation and priority review do not change the standards for approval. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA’s priority review procedures.

Current and future legislation may increase the difficulty and cost for us to commercialize our product candidates, if approved, and affect the prices we may obtain.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In March 2010, the Patient Protection and Affordable Care Act (ACA) was enacted, which includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. The ACA continues to significantly impact the United States' pharmaceutical industry. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, various portions of the ACA have been subject of legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court. The Supreme Court of the United States held oral arguments on the Fifth Circuit Court case in November 2020 and is expected to issue a decision later in 2021. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how this Supreme Court decision, future litigation, and healthcare measures promulgated by the Biden administration will impact the ACA, our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through the end of 2021, unless additional Congressional action is taken.

Moreover, there has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In 2020, under the Trump administration, HHS and CMS issued final rules in November and December of 2020 that were expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of the rules. In January 2021, the Biden administration issued a "regulatory freeze" memorandum that directs department and agency heads to review new or pending rules of the Trump administration. The impact of these lawsuits as well as legislative, executive, and administrative actions of the current administration on us and the biopharmaceutical industry as a whole is currently unknown. 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 are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability, or commercialize our product candidates, if approved.

In the European Union similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, an adequate level of reimbursement might not be available for such products and third-party payors' reimbursement policies might adversely affect our ability to sell any future products profitably.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biologic therapeutics. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. 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-approval testing and other requirements.

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, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to:

- comply with the laws of the FDA, EMA, and other comparable foreign regulatory authorities;
- provide true, complete, and accurate information to the FDA, EMA, and other comparable foreign regulatory authorities;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or
- report financial information or data accurately or to disclose unauthorized activities to us.

If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education, and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations, and financial conditions could be adversely affected.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be subject to various federal and state fraud and abuse laws. The laws that may impact our operations include the following:

- The federal Anti-Kickback Statute which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.
- Federal civil and criminal false claims laws, including the False Claims Act, which can be enforced through civil “qui tam” or “whistleblower” actions, and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease, or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.
- The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information.
- The federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, require applicable manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the HHS under the Open Payments Program, information related to certain payments or other transfers of value made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The information reported annually is publicly available on a searchable website. Effective January 1, 2022, for data reported to CMS in 2022 and collected in 2021, reporting obligations of applicable manufacturers with respect to payments and transfers of value made to covered recipients have been extended to include additional covered recipients, including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives.

- Analogous state and foreign laws and regulations, such as state and foreign anti-kickback and false claims laws, may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements, as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers.
- State laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources.
- State and local laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensation and other remuneration, and items of value provided to healthcare professionals and entities.
- State and local laws that require the registration of pharmaceutical sales representatives.
- State and foreign laws that govern the privacy and security of personal information (including health information) in certain circumstances. These include, but are not limited to, the EU General Data Protection Regulation, and the California Consumer Privacy Act, as amended and expanded by the California Privacy Rights Act, each of which is discussed below. Many of these laws governing the privacy and security of personal information differ from each other in significant ways and may not have the same effects or obligations, thus complicating compliance efforts.

In addition, we are subject to federal and state consumer protection and unfair competition laws that broadly regulate marketplace activities and activities that potentially harm consumers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

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

Our business activities may be subject to the Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

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. These laws generally prohibit companies and their employees and third party business partners, representatives and agents from engaging in corruption and bribery, including offering, promising, giving, or authorizing the provision of anything of value, either directly or indirectly, to a government official or commercial party in order to influence official action, direct business to any person, gain any improper advantage, or 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 government officials, including officials of non-U.S. governments. Additionally, in many countries, healthcare providers are employed by the government, and the purchasers of biopharmaceuticals are government entities; therefore, our dealings with these providers and purchasers are subject to regulation and such healthcare providers and employees of such purchasers may be considered "foreign officials" as defined in the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology companies. In addition to our own employees, we leverage third parties to conduct our business abroad, such as obtaining government licenses and approvals. We and our third-party business partners, representatives and agents may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities and we may be held liable for the corrupt or other illegal activities of our employees, our third-party business partners, representatives and agents, even if we do not explicitly authorize such activities. There is no certainty that our employees or the employees of our third-party business partners, representatives and agents 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 whistleblower complaints, adverse media coverage, investigations, loss of export privileges, debarment from U.S. government contracts, substantial diversion of management's attention, significant legal fees and fines, severe criminal or civil 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 products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, financial condition and stock price.

In addition, our products 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 products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our business. Furthermore, U.S. export control laws and economic sanctions prohibit the provision 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.

Data collection under European and U.S. laws is governed by restrictive regulations addressing the collection, use, processing and, in the case of Europe, cross-border transfer, of personal information.

We may collect, process, use or transfer personal information from individuals located in the European Union in connection with our business, including in connection with conducting clinical trials in the European Union. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the European Union. The collection and use of personal health data in the European Union are governed by laws, regulations, and directives, including the General Data Protection Regulation (EU) 2016/679 (GDPR). This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside of the European Economic Area, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. This legislation imposes significant responsibilities and liabilities in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance. Any actual or alleged failure to comply with the requirements of the GDPR or other laws, regulations, and directives of the member states of the European Union may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, U.S. states are adopting new laws or amending existing laws and regulations, requiring attention to frequently changing regulatory requirements applicable to data related to individuals. For example, California has enacted the California Consumer Privacy Act (CCPA), which took effect on January 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. The CCPA

gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and which can include any of our current or future employees who may be California residents or any other California residents whose data we collect or process) and provide such residents new ways to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. As we expand our operations and trials (both preclinical or clinical), the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. Other states are beginning to consider and pass similar laws.

Additionally, a new privacy law, the California Privacy Rights Act (CPRA), was approved by California voters in the election on November 3, 2020. The CPRA creates obligations relating to consumer data beginning on January 1, 2022, with implementing regulations expected on or before July 1, 2022, and enforcement beginning July 1, 2023. The CPRA modifies the CCPA significantly, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. Further, on March 2, 2021, Virginia enacted the Virginia Consumer Data Protection Act (CDPA), a comprehensive privacy statute that becomes effective on January 1, 2023 and shares similarities with the CCPA, CPRA, and legislation proposed in other states. In addition, U.S. and international laws and regulations that have been applied to protect user privacy (including laws regarding unfair and deceptive practices in the U.S. and GDPR in the EU) may be subject to evolving interpretations or applications.

Laws, regulations, and directives relating to privacy and data security are not consistent across jurisdictions, and they may impose conflicting or uncertain obligations. Compliance with laws, regulations, and directives is a rigorous, costly, and time-intensive process, and we may find it necessary or appropriate to put in place additional mechanisms ensuring compliance with new and changing data protection obligations. Actual or alleged noncompliance with any such laws, regulations, and directives may lead to regulatory investigations, enforcement actions and other proceedings, claims, and litigation, with the potential for significant fines, penalties, and other liabilities in the event of actual or alleged noncompliance. Any of these could adversely affect our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary product candidates and other technologies we may develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad relating to our core programs and product candidates, as well as other technologies that are important to our business. Given that the development of our product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our product candidates is also at an early stage. For example, we have filed or intend to file patent applications on aspects of our technology and core product candidates; however, there can be no assurance that any such patent applications will issue as granted patents around the world. The requirements for patentability differ in certain countries, and certain countries have heightened requirements for patentability. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our technology and product candidates and each of these provisional patent applications is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions relating to our core programs and product candidates, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture for protection of such core programs, product candidates, and other technologies. Any changes we make to our product candidates to cause them to have what we view as more advantageous properties may not be covered by our existing patents and patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered product candidates. There can be no assurance that we would be able to secure patent protection that would adequately cover altered product candidates. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our core programs and product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 technology and product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has 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 our product candidates or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Patent applications we own currently or that in the future issue as patents may not be issued 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 to which we have rights may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether product candidates or other technologies 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 materially adversely affect 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. We may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office (USPTO) or post-issuance become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as post-grant review at the USPTO or oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. 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 our product candidates and other technologies. 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. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. Termination of these licenses or reduction or elimination of our rights under these licenses may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these licenses, including our rights to important intellectual property or technology. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product 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.

Some of our patents and patent applications may in the future be co-owned with third parties. In addition, future collaborators or licensors may co-own their patents and patent applications with other third parties with whom we do not have a direct relationship. Our rights to certain of these patents and patent applications may be dependent, in part, on inter-institutional or other operating agreements between the joint owners of such patents and patent applications, who are not parties to our license agreements. If our future collaborators or licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patents or patent applications or we are otherwise unable to secure such exclusive rights, 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 to the extent such products and technology are not also covered by our intellectual property. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology, on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. 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.

If we fail to comply with our obligations under our license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having 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.

Our rights to develop and commercialize our product candidates may be subject, in part, to the terms and conditions of agreements with others.

Agreements we may enter into in the future may not provide exclusive rights to use certain intellectual property and technology retained by the collaborator 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 or other third parties from developing and commercializing competitive products that utilize technology retained by such collaborators to the extent such products are not also covered by our intellectual property.

In addition, subject to the terms of any such agreements, we may not have the right to control the preparation, filing, prosecution, and maintenance, and we may not have the right to control the enforcement and defense of certain patents and patent applications retained by the collaborator and provided to us under a limited license. We cannot be certain that patents and patent applications that are controlled by future collaborators will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our collaborators fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the limited rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our product candidates that are subject of such licensed rights could be adversely affected, and we may have a reduced ability to prevent competitors from making, using, and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from future collaborators, we may still be adversely affected or prejudiced by actions or inactions of future collaborators that took place prior to the date upon which we assumed control over patent prosecution.

We may enter into agreements with future collaborators to option or license certain intellectual property and may need to obtain additional intellectual property rights from others to advance our research or allow commercialization of product candidates we may develop. We may be unable to obtain additional intellectual property rights 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 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 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.

Furthermore, our or our future collaborators' patents may be subject to a reservation of rights by one or more third parties. The U.S. government may have certain rights to resulting intellectual property. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we fail to achieve the practical application of the government funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in facilities in the United States in certain circumstances and if this requirement is not waived. Any exercise by the U.S. government of such rights or by any third-party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

If we fail to comply with our obligations in agreements under which we option or license intellectual property rights from future collaborators or licensors or otherwise experience disruptions to our business relationships with future collaborators or licensors, we could lose intellectual property rights that are important to our business.

We may enter into agreements with future collaborators that impose various economic, development, diligence, commercialization, and other obligations on us. Such collaboration agreements may also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products. Our future collaborators might conclude that we have materially breached our obligations under such agreements and might therefore terminate or seek damages under the agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these agreements. Termination of these agreements could cause us to lose the rights to certain patents or other intellectual property, or the underlying patents could fail to provide the intended exclusivity, and competitors or other third parties may have the freedom to seek regulatory approval of, and to market, products similar to or identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and growth prospects.

Moreover, disputes may arise regarding intellectual property subject to a collaboration agreement, including:

- the scope of the option or license rights granted under the agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the collaborator that is not subject to the option or license rights granted under the agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our collaborators and us and our other partners; and
- the priority of invention of patented technology.

We may enter into agreements to option or license intellectual property or technology from third parties that 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 have a material adverse effect on our business, financial condition, results of operations, and growth prospects. Moreover, if disputes over intellectual property that we have optioned or licensed prevent or impair our ability to maintain such arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and growth prospects.

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

Filing, prosecuting, and defending patents on our product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Consequently, we may not be able to prevent third parties from using 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 products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and 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 at risk of being invalidated or interpreted narrowly, could put our patent applications 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 and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Issued patents covering our product candidates and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we initiated legal proceedings against a third-party to enforce a patent covering our product candidates or other technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our product candidates or other technologies. 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, of which we and the patent examiner were unaware during prosecution. 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 product candidates or other technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and growth prospects.

Third-party claims of intellectual property infringement, misappropriation, or other violation against us may prevent or delay the development and commercialization of our product candidates and other technologies.

The fields of designing and developing treatments for immunology, inflammation, and metabolic diseases are highly competitive and dynamic. In addition, while research and development that is taking place by several companies, including us and our competitors in oral biologic therapeutics, the technology used in our product candidates is still in its infancy and no products utilizing similar technology have yet reached the market. As such, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. This could lead to significant intellectual property related litigation and proceedings relating to our, and other third-party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our ability to develop, manufacture, market, and sell any product candidates that we develop and to use our proprietary technologies without infringing, misappropriating, and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, post-grant review, *inter partes* review, derivation proceedings, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may become party to, or threatened with, such actions in the future, regardless of their merit.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third-party, for example, a competitor in the fields in which we are developing product candidates, and other technologies might assert are infringed by our current or future product candidates or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates or other technologies may infringe.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our product candidates or other technologies infringes upon these patents. In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our product candidates or other technologies. In this case, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing product candidates or other technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates or other technologies, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated, or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

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

Competitors may infringe our patents or we may be required to defend against claims of infringement. In addition, our patents may become involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent in which we have an interest is invalid or unenforceable, the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1), or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Patent terms may be inadequate to protect our competitive position on our products and services for an adequate amount of time.

Patents have a limited lifespan. In the United States and abroad, if all maintenance fees/annuity fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date. The protection a patent affords is limited. Even if patents covering our products 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 products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

We may be subject to claims that former employees or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, our Co-Founder and Chief Scientific Officer, Dr. Randall Mrsny, has been and remains an employee of both our company and the University of Bath, and as such, we must ensure that we own our intellectual property that is conceived or developed by Dr. Mrsny and that which he is under obligation to assign to our company. We may have inventorship or ownership disputes arise from conflicting obligations of our founders, employees, consultants, or others who are involved in developing our product candidates or other technologies, such as with the University of Bath. Litigation may be necessary to defend against any claims challenging inventorship or ownership of our patents, trade secrets, or other intellectual property. If the defense of any such claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. Even if we are successful in defending against any such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act). The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and growth prospects could be materially harmed.

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

In addition to seeking patents for our product candidates and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We consider trade secrets and know-how to be one of our primary sources of intellectual property. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

While we seek to protect these trade secrets and other proprietary technology, we cannot guarantee that we have entered into non-disclosure, confidentiality, invention, or patent assignment agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor 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 our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be materially and adversely harmed.

If any of our patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents with respect to our product candidates. With respect to our intellectual property related to our product candidates, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is 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. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Any parties who enter into nondisclosure and confidentiality agreements with us who have access to confidential or patentable aspects of our research and development output, such as our employees, CROs, CDMOs, consultants, advisors, and other third parties, may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, 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 any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Intellectual property rights do not necessarily address all potential threats.

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:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;

- we, or our future licensors or collaborators, might 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 owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties 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 harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it or they could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted on September 16, 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or other technologies or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and growth 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 may be adversely affected.

Our registered or unregistered 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 or other third parties 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 may be adversely affected. 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 adversely affect our business, financial condition, results of operations, and growth prospects. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. In certain countries outside of the United States, trademark registration is required to enforce trademark rights. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Risks Related to Our Operations

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate, and retain highly qualified managerial, scientific, and medical personnel. We are highly dependent on our management and our scientific, technical, business, and medical personnel. The loss of the services provided by any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business. Additionally, the COVID-19 pandemic may interfere with our ability to hire or retain personnel.

We conduct our operations at our facility in South San Francisco, California, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, manufacturing, and sales and marketing personnel, and we face significant competition for experienced personnel. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited talent pool in our industry due to the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of our region, and doing so may be costly and difficult.

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 can offer. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. 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. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

Future strategic partnerships and collaborations may be important to us. We will face significant competition in seeking new strategic partners.

We have limited capabilities for manufacturing and do not yet have any capability for sales, marketing or distribution. For some of our product candidates, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. The competition for strategic partners is intense. Our ability to reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner's evaluation of a number of factors. These 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 products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The strategic partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such collaboration could be more attractive than the one with us for our product candidate.

Strategic partnerships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future strategic partners. Even if we are successful in entering into collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements with other potential collaborators.

If we are unable to reach agreements with suitable strategic partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay 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 fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into strategic partnerships and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our technology platform and our business may be materially and adversely affected. Any collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the partner terminates the collaboration. Any such collaboration, or other strategic transaction, may require us to incur non-recurring or other charges, and increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material and adverse effect on our business, financial condition, results of operations, and prospects. Conversely, any failure to enter any collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches the market.

If we are unable to maintain future strategic partnerships, or if these strategic partnerships are not successful, our business could be adversely affected.

Any future strategic partnerships we enter into may pose a number of risks, including the following:

- we may not be able to enter into critical strategic partnerships or enter them on favorable terms;
- strategic partners have significant discretion in determining the effort and resources that they will apply to such a partnership, and they may not perform their obligations as agreed or expected;
- strategic partners may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the partners' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- strategic partners 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;
- strategic partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the strategic partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than our product candidates;
- product candidates discovered in collaboration with us may be viewed by our strategic partners as competitive with their own product candidates or products, which may cause strategic partners to cease to devote resources to the commercialization of our product candidates;
- a strategic partner with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidates;
- disagreements with strategic partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- strategic partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- strategic partnerships may be terminated for the convenience of the partner and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

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

We may engage in various acquisitions, collaborations, and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any acquisition, collaboration, or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- volatility with respect to the financial reporting related to such arrangements;
- assumption of indebtedness or contingent liabilities;
- issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products, and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- 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 regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology, and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, 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.

Any legal proceedings or claims against us could be costly and time-consuming to defend and could harm our reputation regardless of the outcome.

We are and may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, including intellectual property, product liability, employment, class action, whistleblower and other litigation claims, and governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability, or require us to change our business practices. In addition, the expense of litigation and the timing of this expense from period to period are difficult to estimate, subject to change, and could adversely affect our financial condition and results of operations. Because of the potential risks, expenses, and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Any of the foregoing could adversely affect our business, financial condition, and results of operations.

Our business is subject to economic, political, regulatory, and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Some of our CDMOs are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in certain non-U.S. economies and markets;
- differing and changing regulatory requirements in non-U.S. countries, including drug pricing and reimbursement requirements;
- 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;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs, and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements, or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;

- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- potential liability under the FCPA, U.K. Bribery Act, or comparable foreign laws; and
- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or outbreaks of health epidemics such as the COVID-19 pandemic.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain profitable operations.

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

As of December 31, 2020, we had federal and California net operating loss (NOLs) carryforwards of approximately $156.0 million. The federal NOLs carryforwards arising in the tax year ending December 31, 2017 and earlier tax years will begin to expire in 2036, if not utilized. Realization of these NOLs depends on future income, and there is a risk that our existing NOLs could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our operating results.

Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change NOLs carryforwards and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. As a result of our private placements, our IPO in June 2020, and other transactions that have occurred since our incorporation, we may have experienced such an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control.

As a result, our ability to use our pre-change NOLs carryforwards and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

Changes in our effective tax rate or tax liability may have an adverse effect on our operating results.

Our effective tax rate and the amount of our taxable income could be adversely affected by several factors, many of which are outside of our control, including:

- changes in the relative amounts of income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates;
- changes in tax laws, rates, tax treaties, and regulations or the interpretation of them;
- changes to our assessment about our ability to realize our deferred tax assets that are based on estimates of our future results, the prudence and feasibility of possible tax planning strategies, and the economic and political environments in which we do business;
- changes to the financial accounting rules for income tax;
- the tax effects of acquisitions;
- the outcome of current and future tax audits, examinations, or administrative appeals; and
- limitations or adverse findings regarding our ability to do business in some jurisdictions.

For example, the Biden administration recently proposed to increase the U.S. corporate income tax rate from 21% to 28%, increase U.S. taxation of international business operations, and impose a global minimum tax. Any of these developments or changes in federal, state, or international tax laws or tax rulings could adversely affect our effective tax rate and our operating results.

Risks Related to Ownership of Our Common Stock

An active trading market of our common stock may not be sustained.

Prior to the closing of our IPO in June 2020, there was no public trading market for our common stock. Although our common stock is listed on the Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. We cannot

predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock may be volatile, which could result in substantial losses for investors.

The trading price of our common stock may be highly volatile and subject to wide fluctuation in response to various factors, some of which are beyond our control. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive products or technologies;
- the timing and results of preclinical studies and clinical trials for our current product candidates and any future product candidates that we may develop;
- failure or discontinuation of any of our product development and research programs;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of 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 level of expenses related to any of our research programs, clinical development programs, or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- expiration of market standoff or lock-up agreements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, political, and market conditions, including the impact of the COVID-19 pandemic and fiscal and monetary stimulus measures to counteract the impact of the COVID-19 pandemic; and
- the other factors described in this “Risk Factors” section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock or if we fail to meet their operating results estimates for us, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

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

Moreover, certain holders of shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act of 1933, as amended (Securities Act) would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances, and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing such securities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, or nature of any future offerings. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

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

As of March 31, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 78% of our voting stock. As a result, this group of stockholders, if they act together, will have the ability to control 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 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 common stock, and might affect the prevailing market price for our common stock.

We are an "EGC" and the reduced disclosure requirements applicable to EGC may make our common stock less attractive to investors.

We are an "EGC" as defined in the JOBS Act. For so long as we remain an EGC, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (SOX), 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, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would

otherwise apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we are no longer an EGC or 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 new or revised accounting pronouncements as of public company effective dates.

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

As a public company, and particularly after we are no longer an EGC, we have incurred and will continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. SOX, the Dodd-Frank Wall Street Reform, and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will need to continue to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to SOX Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC. However, while we remain an EGC, 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 SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing 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 we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We have previously identified material weaknesses in our internal control over financial reporting and if we are unable to maintain effective internal controls or if we identify additional material weaknesses in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business, financial position and results of operations.

In connection with the audit of our financial statements for the year ended December 31, 2018, 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 annual or interim financial statements will not be prevented or detected and corrected on a timely basis. The material weakness was that we: (i) lacked a sufficient number of qualified personnel in our accounting function to adequately execute reviews of transactions and segregate duties; and (ii) did not design and maintain effective controls over segregation of duties related to manual journal entries. Specifically, certain personnel had the ability to both prepare and post manual journal entries without independent review by someone without the ability to prepare and post journal entries. Additionally, the same personnel with the ability to prepare and post manual journal entries was responsible for performing reviews of financial statement fluctuations period over period.

During 2019, we took certain actions that remediated the material weakness that was identified in connection with the audit for the year ended December 31, 2018, which included hiring management-level personnel with technical accounting expertise, engaging external third-party resources to assist in execution of transactions which has allowed us to design adequate review procedures in our accounting and finance organization including design of controls with appropriate segregation of duties, and identifying and implementing improved processes and controls.

We have begun taking measures and plan to continue to take measures to design and implement an effective control environment. However, we cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate or prevent future material weaknesses. If we are unable to successfully maintain internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected. In addition, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, when required, investors may lose confidence in the accuracy and completeness of our financial reports, we may face restricted access to the capital markets, and our stock price may be materially adversely affected. Moreover, we could become subject to investigations by regulatory authorities, which could require additional financial and management resources.

If we are unable to maintain effective internal controls, our business, financial position, and results of operations could be adversely affected.

As a public company, we are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended (Exchange Act), including the requirements of SOX Section 404, which require annual management assessments of the effectiveness of our internal control over financial reporting. However, our auditors will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to SOX Section 404 until we are no longer an EGC if we continue to take advantage of the exemptions available to us through the JOBS Act.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by SOX. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position, and results of operations.

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

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

Delaware law and provisions in our amended and restated certificate of incorporation and bylaws might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

- establish that our board of directors is divided into three classes, Class I, Class II, and Class III, with each class serving staggered three-year terms;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;

- provide that our directors may only be removed for cause;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issues shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum 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 bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws (as either may be amended from time to time), or (iv) any action asserting a claim governed by the internal affairs doctrine, except, in each case, (A) any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten days following such determination), (B) which is vested in the exclusive jurisdiction of a court or forum other than such court, or (C) for which such court does not have subject matter jurisdiction.

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, employees, control persons, underwriters, or agents, which may discourage lawsuits against us and our directors, employees, control persons, underwriters, or agents. Additionally, a court could determine that the exclusive forum provision is unenforceable, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. If a court were to find these provisions of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, or results of operations.

General Risk Factors

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer other breakdowns, cyberattacks, or information security breaches that could compromise the confidentiality, integrity, and availability of such systems and data, and affect our reputation.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors may be vulnerable to damage, compromise, and unauthorized access owing to a variety of causes, including system malfunction, natural disasters, terrorism, war and telecommunication and electrical failure, and inadvertent or intentional actions by our employees,

CROs and other contractors, and/or other third parties, or cyber-attacks by malicious third parties. As the cyber-threat landscape evolves, such cyberattacks are growing in frequency, sophistication, and intensity, and are becoming increasingly difficult to detect. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering, and/or other means. These risks may increase as a result of COVID-19, owing to an increase in our and our CROs' and other contractors' personnel working remotely. If a breakdown, disruption, cyberattack, or other information security breach or security incident were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, which could lead to significant delays or setbacks in our research. For example, the loss of clinical trial data from completed, ongoing, or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, disruptions of, or security breaches or other incidents of, our information technology systems or those of our future CROs and other contractors and consultants could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure or dissemination of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to loss, damage, or unauthorized access to, or use, alteration, or disclosure or dissemination of, personal information, including personal information regarding clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of or access to confidential or proprietary information, including data related to clinical trial subjects or our personnel, or if it were perceived that any of those had occurred, we could incur liability and the further development and commercialization of our product candidates could be delayed. There can be no assurance that we, our CROs or other contractors, or our business counterparts will be successful in efforts to detect, prevent, or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data, which could result in financial, legal, business, or reputational harm to us. Further, notification and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or other security incident.

We also rely on third parties to manufacture our product candidates, and similar events relating to their information technology systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in any loss, destruction, or alteration of, or damage or unauthorized access to, our data or other information that is processed or maintained for us, or inappropriate disclosure or dissemination of any such information, we could be exposed to claims, litigation, governmental investigations and proceedings, we could face delays in further development and commercialization of our product candidates, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

The insurance we maintain may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CDMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical or health epidemics, and other natural or man-made disasters or business interruptions, for which we are partly uninsured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

The majority of our operations including our corporate headquarters are located in a facility in South San Francisco, California. Damage or extended periods of interruption to our corporate, development, or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry, or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

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

The market price of our 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. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds from Public Offering of Common Stock

On June 4, 2020, our registration statement on Form S-1 was declared effective by the SEC for our initial public offering of common stock. We began trading on the Nasdaq Global Select Market on June 5, 2020, and the transaction formally closed on June 9, 2020. In connection with our IPO, we issued and sold an aggregate of 12,650,000 shares of our common stock at a price of $14.00 per share, including 1,650,000 shares of our common stock issued and sold in connection with the full exercise by the underwriters of their option to purchase additional shares of common stock. The aggregate offering price for shares sold in our IPO was $177.1 million. The joint book-running managers for the initial public offering were BofA Securities, Inc., Jefferies LLC, and SVB Leerink LLC. After deducting underwriting discounts and commissions and offering costs paid by us of approximately $16.5 million, the net proceeds from the offering were approximately $160.6 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors pursuant to our director compensation policy.

There has been no material change in the planned use of proceeds in our IPO as described in our final prospectus filed with the SEC on June 5, 2020 pursuant to Rule 424(b)(4). We invested the funds received in interest-bearing investment-grade securities.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.1	Lease Agreement between ARE-East Jamie Court, LLC and Applied Molecular Transport Inc. dated February 5, 2021	8-K	001-39306	10.1	February 10, 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 Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith			
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith			
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.	Furnished herewith			
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.	Furnished herewith			
101.INS	XBRL Instance Document	Filed herewith			
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith			

†The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Applied Molecular Transport Inc.

Date: May 13, 2021

By: /s/ Tahir Mahmood

Tahir Mahmood, Ph.D.

Co-Founder and Chief Executive Officer

Date: May 13, 2021

By: /s/ Shawn Cross

Shawn Cross

Chief Financial Officer

Exhibit 31.1

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

I, Tahir Mahmood, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Applied Molecular Transport 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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 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 13, 2021

By: /s/ Tahir Mahmood
Tahir Mahmood, Ph.D.
Co-Founder, Chief Executive Officer and Director (Principal Executive Officer)

Exhibit 31.2

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

I, Shawn Cross, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Applied Molecular Transport 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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 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 13, 2021

By: /s/ Shawn Cross
Shawn Cross
Chief Financial Officer
(Principal Financial Officer)

Exhibit 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

In connection with the Quarterly Report of Applied Molecular Transport Inc. (the "Company") on Form 10-Q for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Tahir Mahmood, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: May 13, 2021

By: /s/ Tahir Mahmood

Tahir Mahmood, Ph.D.

Co-Founder, Chief Executive Officer and Director (Principal Executive Officer)

Exhibit 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

In connection with the Quarterly Report of Applied Molecular Transport Inc. (the "Company") on Form 10-Q for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Shawn Cross, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: May 13, 2021

By: /s/ Shawn Cross
Shawn Cross
Chief Financial Officer
(Principal Financial Officer)