

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended 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: 001-39661

ATEA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
125 Summer Street
Boston, MA
(Address of principal executive offices)

46-0574869
(I.R.S. Employer
Identification No.)

02110
(Zip Code)

(857) 284-8891
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	AVIR	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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of May 13, 2021, the registrant had 82,736,937 shares of common stock, \$0.001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. The words “aim,” “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” “on track,” “plan,” “possible,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our expectations relating to clinical trials for our product candidates, including projected costs, study designs or the timing for initiation, recruitment, completion, or reporting top-line data;
- the potential therapeutic benefits of our product candidates and the potential indications and market opportunities therefor;
- the safety profile and related adverse events of our product candidates;
- our plans to research, develop and commercialize our current and future product candidates;
- the potential benefits of our collaboration with Roche or any future collaboration we may enter into with Roche or others;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we may receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our estimates regarding future revenue, expenses and results of operations;
- the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;
- our future financial position, capital requirements and needs for additional financing;
- our business strategy;
- developments relating to our competitors, competing treatments and vaccines and our industry;
- our expectations regarding federal, state and foreign laws and regulations;
- our ability to attract, motivate, and retain key personnel; and
- the impact of the COVID-19 pandemic on our business, including our preclinical studies and clinical trials.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Factors that may cause actual results to differ materially from current expectations include the initiation, execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from our clinical trials, ongoing discussions with and actions by regulatory authorities, our development activities and those other factors we discuss in Part II, Item 1A. “Risk Factors.” You should read these factors and the other cautionary statements made in this report as being applicable to all related forward-looking statements wherever they appear in this report. These risk factors are not exhaustive and other sections of this report may include additional factors which could adversely impact our business and financial performance. Given these uncertainties, you should not rely on these forward-looking statements as predictions of future events. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

As used in this Quarterly Report on Form 10-Q, unless otherwise specified or the context otherwise requires, the terms “we,” “our,” “us,” the “Company” refer to Atea Pharmaceuticals, Inc. and its subsidiary. All brand names or trademarks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. The principal risks and uncertainties affecting our business include the following:

- There is significant uncertainty around our development of AT-527 as a potential treatment for COVID-19.
- We are highly dependent on our management, directors and other key personnel.
- We may expend resources in anticipation of potential clinical trials and commercialization of AT-527, which we may not be able to recover if AT-527 is not approved for the treatment of COVID-19 or we are not successful at commercializing AT-527.
- The market for therapeutics for the treatment of COVID-19 may be reduced, perhaps significantly, as uptake of vaccines that are effective in providing immunity continues to increase.
- AT-527 may face significant competition from other treatments for COVID-19 that are currently marketed or are in development.
- The COVID-19 pandemic continues to rapidly evolve and may materially and adversely affect our other business opportunities and financial results.
- We have a limited operating history and no history of successfully developing or commercializing any approved antiviral products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability.
- We have incurred significant losses since inception. We expect our expenditures will increase for the foreseeable future. We have no products that have generated any commercial revenue and we may never achieve or maintain sustainable profitability.
- We will require substantial additional financing, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- Our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income may be subject to certain limitations.
- Our business is highly dependent on the success of our most advanced product candidates. If these product candidates fail in preclinical or clinical development, do not receive regulatory approval or are not successfully commercialized, or are significantly delayed in doing so, our business will be harmed.
- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory authorities are lengthy, expensive, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be seriously harmed. Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us, our current collaboration partner, Roche, or any future collaboration partners from obtaining approvals for the commercialization of any product candidate we develop.
- Clinical development is lengthy and uncertain. We may encounter substantial delays and costs in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.
- Our product candidates may be associated with serious adverse events, 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.
- We currently conduct clinical trials, and may in the future choose to conduct additional clinical trials, of our product candidates in sites outside the United States, and the FDA may not accept data from trials conducted in foreign locations.
- Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

- We may not be successful in our efforts to identify and successfully develop additional product candidates.
- Risks related to healthcare laws and other legal compliance matters may materially and adversely affect our business and financial results.
- Risks related to commercialization may materially and adversely affect our business and financial results.
- Risks related to manufacturing and our dependence on third parties may materially and adversely affect our business and financial results.
- Risks related to intellectual property may materially and adversely affect our business and financial results, including if we are unable to obtain, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and product candidates, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.
- We have only a limited number of employees which may be inadequate to manage and operate our business.
- Our business and operations would suffer in the event of system failures, deficiencies or intrusions.
- We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.
- We may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause us to incur debt or assume contingent liabilities, and subject us to other risks.
- We or the third parties upon whom we depend may be adversely affected by natural disasters or other unforeseen events resulting in business interruptions and our business continuity and disaster recovery plans may not adequately protect us from such business interruptions.
- Litigation against us could be costly and time-consuming to defend and could result in additional liabilities.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.
- Risks related to our common stock may materially and adversely affect our stock price.
- If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.
- We could be subject to securities class action litigation.

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Item 1. Financial Statements.

ATEA PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share amounts)
(Unaudited)

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 833,751	\$ 850,117
Unbilled other receivable	—	5,815
Prepaid expenses and other current assets	6,394	7,545
Total current assets	840,145	863,477
Property and equipment, net	41	48
Other assets	463	107
Total assets	\$ 840,649	\$ 863,632
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	3,792	60
Accrued expenses and other current liabilities	15,104	14,368
Deferred revenue	235,382	301,367
Total current liabilities	254,278	315,795
Other liabilities	113	36
Total liabilities	254,391	315,831
Commitments and contingencies (see Note 11)		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share; 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 300,000,000 shares authorized as of March 31, 2021 and December 31, 2020, respectively; 82,736,937 and 82,436,937 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	83	82
Additional paid-in capital	620,622	612,879
Accumulated deficit	(34,447)	(65,160)
Total stockholders' equity	586,258	547,801
Total liabilities and stockholders' equity	\$ 840,649	\$ 863,632

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

ATEA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended	
	March 31,	
	2021	2020
Collaboration revenue	\$ 65,985	\$ —
Operating expenses		
Research and development	26,571	2,821
General and administrative	8,759	1,224
Total operating expenses	35,330	4,045
Income (loss) from operations	30,655	(4,045)
Interest income and other, net	58	57
Net income (loss) and comprehensive income (loss)	\$ 30,713	\$ (3,988)
Net income (loss) per share attributable to common stockholders		
Basic	\$ 0.37	\$ (0.40)
Diluted	\$ 0.34	\$ (0.40)
Weighted-average common shares outstanding		
Basic	82,577,836	10,091,000
Diluted	89,099,075	10,091,000

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

ATEA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except share amounts)

(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance—December 31, 2020	—	\$ —	82,436,937	\$ 82	\$ 612,879	\$ (65,160)	\$ 547,801
Issuance of common stock upon exercise of stock options			300,000	1	470	—	471
Stock-based compensation expense	—	—	—	—	7,273	—	7,273
Net income (loss)	—	—	—	—	—	30,713	30,713
Balance—March 31, 2021	—	\$ —	82,736,937	\$ 83	\$ 620,622	\$ (34,447)	\$ 586,258

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance—December 31, 2019	33,645,447	\$ 69,114	10,091,100	\$ 10	\$ 4,632	\$ (54,213)	\$ (49,571)
Stock-based compensation expense	—	—	—	—	189	—	189
Net income (loss)	—	—	—	—	—	(3,988)	(3,988)
Balance—March 31, 2020	33,645,447	69,114	10,091,100	\$ 10	\$ 4,821	\$ (58,201)	\$ (53,370)

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

ATEA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Three Months Ended	
	March 31,	
	2021	2020
Cash flows from operating activities		
Net income (loss)	\$ 30,713	\$ (3,988)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation expense	7,273	189
Depreciation and amortization expense	7	4
Changes in operating assets and liabilities:		
Unbilled accounts receivable	—	—
Prepaid expenses and other current assets	1,151	(192)
Other assets	(356)	—
Accounts payable	3,732	(150)
Accrued expenses and other liabilities	6,628	(371)
Deferred revenue	(65,985)	—
Net cash used in operating activities	(16,837)	(4,508)
Cash flows from investing activities		
Additions to property and equipment	—	—
Net cash used in investing activities	—	—
Cash flows from financing activities		
Cash flows from financing activities		
Proceeds from issuance of common stock for exercise of stock options	471	—
Payments made for initial public offering costs	—	(6)
Net cash provided by (used in) financing activities	471	(6)
Net decrease in cash, cash equivalents and restricted cash	(16,366)	(4,514)
Cash, cash equivalents and restricted cash at the beginning of period	850,224	21,768
Cash, cash equivalents and restricted cash at the end of period	\$ 833,858	\$ 17,254
Cash, cash equivalents and restricted cash at the end of period		
Cash and cash equivalents	\$ 833,751	\$ 17,147
Restricted cash	107	107
Total cash, cash equivalents and restricted cash	\$ 833,858	\$ 17,254

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

ATEA PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

(in thousands, except share and per share amounts)

(Unaudited)

1. Nature of Business

Background

Atea Pharmaceuticals, Inc., together with its subsidiary Atea Pharmaceuticals Securities Corporation, is referred to on a consolidated basis as "the Company".

The Company is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing antiviral therapeutics to improve the lives of patients suffering from life-threatening viral infections.

On November 3, 2020, the Company completed an initial public offering of its common stock (the "IPO"). In connection with the IPO, the Company issued 14,375,000 shares of its common stock at \$24.00 per share for net proceeds of \$317,605 after deducting underwriting discounts and commissions and offering expenses. Upon closing of the IPO, all outstanding shares of the Company's convertible preferred stock converted into 57,932,090 shares of common stock.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to clinical-stage biopharmaceutical companies. These risks include, but are not limited to, potential failure of preclinical and clinical studies, uncertainties associated with research and development activities generally, competition from technical innovations of others, dependence upon key personnel, compliance with governmental regulations, the need to obtain marketing approval for any product candidate that the Company may discover and develop, the need to gain broad acceptance among patients, payers and health care providers to successfully commercialize any product for which marketing approval is obtained and the need to secure and maintain adequate intellectual property protection for the Company's proprietary technology and products. Further, the Company is currently dependent on third-party service providers for much of its preclinical research, clinical development and manufacturing activities. Product candidates currently under development will require significant amounts of additional capital, additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. Even if the Company is able to generate revenues from the sale of its product candidates, if approved, it may not become profitable or be able to sustain profitability. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce its operations. The Company is also subject to risks associated with the COVID-19 global pandemic, including actual and potential delays associated with certain of its ongoing and anticipated trials, and potential negative impacts on the Company's business operations and its ability to raise additional capital to finance its operations.

The Company may seek additional capital through one or more of a combination of financing through the sale of additional equity securities, debt financing, or funding in connection with any additional collaborative relationships it may enter into or other arrangements. There can be no assurance that the Company will be able to obtain such additional funding, on terms acceptable to the Company, on a timely basis or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's existing shareholders. The Company believes that its cash and cash equivalents of \$833,751 as of March 31, 2021 will be sufficient to fund its operations as currently planned through at least 2023.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited interim condensed consolidated financial statements of the Company included herein have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") as found in the Accounting Standards Codification ("ASC"), Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB") and the rules and regulations of the Securities and Exchange Commission

("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2020 included in the Company's Annual Report on Form 10-K filed with the SEC on March 30, 2021.

Use of Estimates

The preparation of unaudited financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and in these accompanying notes. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors and assumptions that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, which include but are not limited to estimates of revenue recognition, accrued research and development expenses and the valuation of common stock in connection with the issuance of stock-based awards prior to the Company's IPO. Changes in estimates are recorded in the period in which they become known.

Principles of Consolidation

The unaudited consolidated financial statements include the accounts of Atea Pharmaceuticals, Inc. and its wholly owned subsidiary, Atea Pharmaceuticals Securities Corporation. All intercompany amounts have been eliminated in consolidation.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet as of March 31, 2021, the condensed consolidated statements of operations and comprehensive income (loss) for the three months ended March 31, 2021 and 2020, the condensed consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the three months ended March 31, 2021 and 2020, and the condensed consolidated statements of cash flows for the three months ended March 31, 2021 and 2020 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2021, the results of its operations for the three months ended March 31, 2021 and 2020 and its cash flows for the three months ended March 31, 2021 and 2020. The results for the three months ended March 31, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, or any other interim period.

Significant Accounting Policies

There were no changes in the Company's significant accounting policies as described in the Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 30, 2021 except as discussed below.

Leases

The Company adopted Accounting Standards Updated ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02" or "ASC 842") effective January 1, 2021, using the modified retrospective method and utilized the effective date as its date of initial application, with prior periods presented in accordance with previous guidance under ASC 840, *Leases* ("ASC 840").

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. The Company has elected not to recognize leases with an original term of one year or less on the condensed consolidated balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable.

Leases that are economically similar to the purchase of assets are generally classified as finance leases; otherwise the leases are classified as operating leases. Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The

interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

Net Income (Loss) Per Share Attributable to Common Stockholders

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including outstanding stock options. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options.

Prior to the Company's IPO in November 2020, basic and diluted net loss per share attributable to common stockholders was determined using the two-class method, which is required for participating securities.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02" or "ASC 842"), which requires a lessee to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available.

In July 2018, an amendment was made that allows companies the option of using the effective date of the new standard as the initial application date (at the beginning of the period in which the new standard is adopted, rather than at the beginning of the earliest comparative period). This update includes a short-term lease exception for leases with a term of 12 months or less, in which a lessee can make an accounting policy election not to recognize the associated lease assets and lease liabilities on its balance sheet.

Additionally, in March 2019, the FASB issued ASU 2019-01 ("ASU No. 2019-01"). ASU No. 2019-01 clarifies the transition guidance related to interim disclosures provided in the year of adoption. Lessees will continue to differentiate between finance leases (previously referred to as capital leases) and operating leases, using classification criteria that are substantially similar to the previous guidance. For lessees, the recognition, measurement, and presentation of expenses and cash flows arising from a lease did not significantly change from previous U.S. GAAP. The modified retrospective method includes several optional practical expedients that entities may elect to apply, as well as transition guidance specific to nonstandard leasing transactions.

As the Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the Jobs Act, the Company adopted the new standard effective January 1, 2021 using the modified retrospective method as of the beginning of the period of the adoption. The Company has elected the package of practical expedients permitted in ASC Topic 842. Accordingly, the Company accounted for its existing operating lease as operating lease under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC Topic 842, (b) whether classification of the operating leases would be different in accordance with ASC Topic 842, or (c) whether the unamortized initial direct costs would have met the definition of initial direct costs in ASC Topic 842 at lease commencement.

The adoption of this standard resulted in the recording of operating lease liabilities and right-of-use assets on the Company's condensed consolidated balance sheet (see Note 9). The adoption of the standard did not have a material effect on the Company's condensed consolidated statements of operations and comprehensive income (loss), condensed consolidated statements of cash flows or condensed consolidated statement of stockholders' equity (deficit).

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with*

Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception (“ASU 2017-11”). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. The Company adopted the standard effective January 1, 2021. The adoption of the standard did not have a material effect on the Company’s condensed consolidated balance sheets, condensed consolidated statements of operations and comprehensive income (loss), condensed consolidated statements of cash flows or condensed consolidated statement of stockholders’ equity (deficit).

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The Company adopted the standard effective January 1, 2021. The adoption of the standard did not have a material effect on the Company’s condensed consolidated balance sheets, condensed consolidated statements of operations and comprehensive income (loss), condensed consolidated statements of cash flows or condensed consolidated statement of stockholders’ equity (deficit).

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements*. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. As an emerging growth company, the Company expects to delay adoption until January 1, 2023 and is evaluating the impact that the adoption of ASU 2016-13 will have on its consolidated financial statements.

3. Collaboration Revenue

Background

In October 2020, the Company licensed to F. Hoffmann-LaRoche Ltd. and Genentech, Inc. (collectively, “Roche”) under a license agreement (the “Roche License Agreement”) ex-US rights to develop and commercialize certain of the Company’s compounds, including AT-527.

The Company is responsible for completing certain ongoing clinical and non-clinical and manufacturing activities at its own expense. These obligations are referred to as the Atea Ongoing Studies and the Atea Manufacturing Obligations, respectively. The parties are collaboratively executing a global development plan intended to support regulatory approvals and are sharing joint development costs equally.

The Roche License Agreement provided for a nonrefundable upfront payment of \$350,000 which the Company received in November 2020. In addition, the Roche License Agreement further provides that Roche is obligated to pay the Company up to \$330,000 in the aggregate upon the achievement of certain development and regulatory milestone events; up to \$320,000 in the aggregate upon the achievement of certain sales based milestone events; and tiered royalties based on annual net sales of the products covered by the agreement, ranging between low double-digits and mid-twenties, subject to certain adjustments and limitations. Further, under the Roche License Agreement, the Company has a one time option to request that Roche co-promote with the Company in the United States products covered by the Roche License Agreement that are successfully developed and commercialized. Roche has the right to terminate the Roche License Agreement for convenience pursuant to the terms of the agreement.

The Company concluded that the License Agreement is under the scope of ASC 808 as both parties will actively participate in a joint operating activity and are exposed to significant risks and rewards that depend on the activity's commercial success. ASC 808 provides that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all of the guidance in ASC 606 should be applied, including recognition, measurement, presentation, and disclosure requirements related to such unit of account. The unit-of-account guidance in ASC 808, which aligns with the guidance in ASC 606 (that is, a distinct good or service) is used when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606. Based on the Company's analysis, it concluded that the delivery of the license to Roche, the performance of the Atea Ongoing Studies and the Atea Manufacturing Obligations should be accounted for under ASC 606. The Company's efforts under the global development plan and certain Atea Manufacturing Obligations in the initial year of the contract, will be accounted for under ASC 808.

The Company concluded that the provision of the license to Roche, the performance of the Atea Ongoing Studies and the Atea Manufacturing Obligations should be combined as one performance obligation as Roche cannot receive the benefit of each promise without the other promises. Specifically, Roche is dependent on the Company's expertise and ability to complete the Atea Ongoing Studies and the Atea Manufacturing Obligations, which cannot be performed by other third parties, in order to exploit the value from the license.

The transaction price consists of the \$350,000 upfront payment. The Company concluded that all other forms of variable consideration, including future development and regulatory milestones should be constrained at contract inception. As part of this conclusion, the Company assessed the stage of development and risk associated with remaining development required to achieve each milestone, including whether the achievement of certain milestones was outside the control of the Company. Sales based milestone payments and royalty payments qualify for the sales based royalty exception and will be recognized when the underlying sale transaction have occurred.

The transaction price is being recognized as collaboration revenue over the period in which the Company performs the Atea Ongoing Studies and the Atea Manufacturing Obligations. The Company concluded that an inputs method based on costs incurred compared to total estimated costs-to-complete approach most faithfully depicts the Company's progress towards completion.

The Company concluded that its efforts to complete the global development plan will be accounted for under ASC 808. The Company will account for expenses incurred and reimbursements made or received from Roche pursuant to ASC 730, *Research and Development*. As such, the Company will expense costs as incurred, including any reimbursements made to Roche, and recognize reimbursement received from Roche as a reduction of research and development expense.

The Company classifies all revenues recognized under the Roche License Agreement as collaboration revenues within the accompanying condensed consolidated statements of operations and comprehensive income (loss). For the three months ended March 31, 2021, the Company recognized collaboration revenue of \$65,985 related to the combined performance obligation. As of March 31, 2021, the Company had deferred revenue of \$235,382 related to the Roche License Agreement. Deferred revenue is classified in current liabilities in the accompanying condensed consolidated balance sheet as of March 31, 2021 as the performance obligation is expected to be completed within twelve months.

For the three months ended March 31, 2021, costs reimbursable by Roche which are reflected as a reduction to operating expenses were \$3,419. The Company recorded research and development expense of \$14,517 related to its share of costs incurred by Roche of which \$8,807 had not been reimbursed by the Company as of March 31, 2021 and was recorded as accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheet. Unbilled receivables related to the Roche Agreement were offset against amounts due to Roche included in accrued expenses and other current liabilities at March 31, 2021.

4. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	Fair Value Measurements as of			
	March 31, 2021			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$ 805,994	\$ —	\$ —	\$ 805,994
Total cash equivalents	\$ 805,994	\$ —	\$ —	\$ 805,994

	Fair Value Measurements as of			
	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$ 846,701	\$ —	\$ —	\$ 846,701
Total cash equivalents	\$ 846,701	\$ —	\$ —	\$ 846,701

The Company's assets with fair value categorized as Level 1 within the fair value hierarchy include money market funds. Money market funds are publicly traded mutual funds and are presented as cash equivalents on the condensed consolidated balance sheets as of March 31, 2021 and December 31, 2020.

There were no transfers among Level 1, Level 2 or Level 3 categories in the three months ended March 31, 2021 and 2020.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	March 31, 2021	December 31, 2020
Research and development	\$ 12,612	\$ 10,546
Professional fees and other	1,668	1,079
Payroll and payroll related	824	2,743
Total accrued expenses and other current liabilities	\$ 15,104	\$ 14,368

6. Common Stock

At March 31, 2021, the authorized capital of the Company included 300,000,000 shares of common stock, of which 82,736,937 shares of common stock were issued and outstanding. On all matters to be voted upon by the holders of common stock, holders of common stock are entitled to one vote per share. The holders of common stock have no preemptive, redemption or conversion rights.

7. Stock-based Compensation

In October 2020, the Company's shareholders approved the Company's 2020 Incentive Award Plan (the "2020 Plan"), which became effective in connection with the Company's initial public offering on October 29, 2020. The 2020 Plan provides for the issuance of up to 7,924,000 shares of common stock and for grant of incentive stock options or other incentive awards to employees, officers, directors and consultants of the Company. The number of shares of common stock that may be issued under 2020 Plan is also subject to increase on the first day of each calendar year equal to the lesser of i) 5% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year or ii) such smaller number of shares as is determined by the board of directors. In January 2021, the shares available under the plan were increased by 4,130,847 shares.

The 2020 Plan replaced and is the successor of 2013 Equity Incentive Plan, as amended (the "2013 Plan"), which provided for the grant of incentive stock options, non-qualified stock options, restricted common stock awards and other awards for up to 7,807,200 shares of common stock to employees, officers, directors and consultants of the Company. Upon the closing of the Company's initial public offering the 2013 Plan was terminated and no further

awards will be made under the 2013 Plan. Any cancellation of outstanding awards at the time of the IPO under the 2013 Plan will be made available for grant under 2020 Plan.

As of March 31, 2021 there were 8,977,597 shares of common stock remaining available for future issuance under the 2020 Plan.

Stock Options

During the three months ended March 31, 2021, the Company granted 2,212,250 options to employees with an aggregate grant date fair market value of \$112,471. No options were granted during the three months ended March 31, 2020.

Stock-based Compensation Expense

Stock-based compensation expense is classified as follows:

	Three Months Ended March 31,	
	2021	2020
Research and development expense	\$ 3,198	\$ 119
General and administrative	4,075	70
Total stock-based compensation expense	\$ 7,273	\$ 189

8. Net Income (Loss) Per Share Attributable to Common Stockholders

Basic and diluted earnings per share are calculated as follows:

	Three Months Ended March 31,	
	2021	2020
Net income (loss)	\$ 30,713	\$ (3,988)
Weighted average common shares outstanding, basic	82,577,836	10,091,000
Dilutive effect of outstanding stock options	6,521,239	—
Weighted average common shares outstanding, diluted	89,099,075	10,091,000
Net income (loss) per share, basic	\$ 0.37	\$ (0.40)
Net income (loss) per share, diluted	\$ 0.34	\$ (0.40)

Stock options for the purchase of 1,532,944 weighted average shares were excluded from the computation of diluted net income per share attributable to common stockholders for the three months ended March 31, 2021 because those options had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the Company's common shares for the period. For the three months ended March 31, 2020, 33,645,447 shares of convertible preferred stock, options to purchase 3,911,633 shares of common stock and 200,000 shares of non-vested restricted common stock have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive.

9. Leases

As of January 1, 2021, the date of adoption of ASC 842, the Company utilized operating classification for its facility lease and recorded a right-of-use asset and lease liability.

The following assets and liabilities are recorded on the Company's balance sheet as of March 31, 2021. The right-of-use asset is included in other assets, the current lease liability is included in accrued expenses and other current liabilities and the non-current lease liability is included in other liabilities, respectively.

	As of March 31, 2021	
Right-of-use asset	\$	356
Current lease liability		323
Non-current lease liability		114

The components of the lease costs for the three months ended March 31, 2021 were as follows:

	Three Months Ended March 31, 2021	
Operating lease costs	\$	70
Variable lease costs		6
Total lease costs	\$	76

The variable lease costs for the three months ended March 31, 2021 include common area maintenance and other operating charges associated with the Company's lease of its principal office facilities in Boston, MA. As the Company's lease does not provide an implicit rate, the Company utilized its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

	As of March 31, 2021	
Remaining lease term (in years)		1.3
Discount rate		7%

Future minimum payments under the Company's operating leases as of March 31, 2021 were as follows:

	As of March 31, 2021	
2021	\$	256
2022		200
Total lease payments		456
Less amount representing implied interest		(19)
Total lease liability	\$	437

10. Income Taxes

During the three months ended March 31, 2021 and 2020, the Company recorded no income tax provision for federal or state income taxes. The Company maintained a full valuation allowance for the three months ended March 31, 2021 and 2020 due to uncertainty regarding future taxable income.

11. Commitments and Contingencies

The Company has an agreement with a consultant that requires payment of a success fee calculated as a percentage of certain product sales, subject to a cumulative maximum payout of \$5.0 million. This success payment is contingent upon the occurrence of future events and the timing and likelihood of such payment is neither probable nor estimable.

Indemnification

The Company enters into certain types of contracts that contingently require the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's bylaws, under which the Company must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship, (ii) contracts under which the Company must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, and (iii) procurement, service or license agreements under which the Company may be required to indemnify vendors, service providers or licensees for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the Company's products, technology, intellectual property or services.

From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on the Company's future business, operating results or financial condition. It is not possible to determine the maximum potential amount potentially payable under these contracts since the Company has no history of prior indemnification claims and the unique facts and circumstances involved in each particular claim will be determinative.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, as well as our audited consolidated financial statements and related notes as disclosed in our Annual Report on Form 10-K, dated December 31, 2020, filed with the Securities and Exchange Commission ("SEC") on March 30, 2021. This discussion contains forward-looking statements based upon current plans, expectations and beliefs involving risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in Part II, Item 1A, "Risk Factors" and other factors set forth in other parts of this Quarterly Report on Form 10-Q.

Overview

We are a clinical stage biopharmaceutical company focused on discovering, developing and commercializing antiviral therapeutics to improve the lives of patients suffering from life threatening viral infections. Leveraging our deep understanding of antiviral drug development, nucleoside biology, and medicinal chemistry, we have built a proprietary purine nucleotide prodrug platform to develop novel product candidates to treat single stranded ribonucleic acid viruses, which are a prevalent cause of severe viral diseases. Currently, we are focused on the development of orally available, potent, and selective nucleotide and nucleoside prodrugs for difficult to treat, life-threatening viral infections, including SARS-CoV-2, the virus that causes COVID-19, dengue virus, chronic hepatitis C infection ("HCV"), and respiratory syncytial virus ("RSV").

AT-527 for the Treatment of COVID-19

Our product candidate for the treatment of patients with COVID-19 is AT-527, an orally administered, novel antiviral agent. In October 2020, we entered into a license agreement ("Roche License Agreement") with F. Hoffmann-LaRoche Ltd. and Genentech, Inc. (together, "Roche") under which we granted to Roche an exclusive license to development and commercialization rights related to certain of our compounds, including AT-527, outside of the United States (other than for certain HCV uses). We, together with our collaborator Roche, initiated in April 2021 a Phase 3 clinical trial to study AT-527 in adult patients with mild or moderate COVID-19 in the outpatient setting (MORNINGSKY). In addition, currently we are evaluating AT-527 for the treatment of patients with mild or moderate COVID-19 in two Phase 2 clinical trials. The first trial is a randomized, double-blind, placebo-controlled Phase 2 clinical trial in approximately 190 adult patients with moderate COVID-19 and one or more risk factors for poor outcomes in a hospitalized setting. We dosed our first patient in September 2020 and expect to report interim virology data from this clinical trial in the second quarter of 2021. The second trial, which is being conducted in collaboration with Roche, is a randomized, double-blind, placebo-controlled Phase 2 clinical trial in up to 220 adult patients with mild or moderate COVID-19 in an outpatient setting (MOONSONG). The first patient in this trial was dosed in February 2021. We expect to report interim virology data from this trial in the second quarter of 2021. We recently reported positive results from a Phase 1 trial which is part of a comprehensive Phase 1 program that includes several clinical trials in healthy volunteers either currently underway or planned.

AT-752 for the Treatment of Dengue

We are developing AT-752, an oral, purine nucleoside prodrug product candidate for the treatment of dengue. AT-752 has shown potent activity against all serotypes tested in preclinical studies. In March 2021, we initiated a randomized, double-blind, placebo-controlled Phase 1a trial to evaluate the safety and pharmacokinetics ("PK") of several different dosages of AT-752 in 50-60 healthy adult subjects. Following the completion of the Phase 1a trial, we expect to initiate in the second half of 2021 a Phase 1b trial of AT-752 in 60-80 adult subjects with dengue virus infection to evaluate antiviral activity, safety and PK. As part of the Roche License Agreement, we agreed that we would not commercialize AT-752 outside the United States unless we enter into a separate agreement with Roche to do so.

AT-787 for the Treatment of Hepatitis C

HCV is a blood-borne, positive sense, ssRNA virus, primarily infecting cells of the liver. HCV is a leading cause of chronic liver disease and liver transplants and spreads via blood transfusion, hemodialysis and needle sticks. We are developing AT-787 for the treatment of chronic HCV infection, including patients with decompensated cirrhosis. AT-787 combines AT-527 with a second generation NS5A inhibitor, AT-777, into a single, oral, pan-genotypic fixed-dose combination therapy. Despite recent advances in treatment, there remains a large underserved HCV patient population which continues to grow. Based on our preclinical and clinical data to date, we believe that AT-787, if approved, could offer potential benefits over currently available treatments, including to

shorten treatment duration in non-cirrhotic and compensated cirrhosis HCV in all genotypes and to eliminate the need for ribavirin in patients with decompensated cirrhosis. We temporarily paused our development program for AT-787 in HCV infected patients at the outset of the COVID-19 pandemic in March 2020. Currently we expect to restart this program in the second half of 2021, starting with our Phase 1/2a clinical trial, which is designed to evaluate the safety and PK of different dosages of AT-777 in healthy adults and evaluate the combination of AT-527 and AT-777.

AT-889 and Other Candidates for the Treatment of RSV

RSV is a seasonal respiratory virus that can be serious for infants, older adults, and the immuno-compromised population. We are evaluating AT-889, a second generation nucleoside pyrimidine prodrug and other compounds for the treatment of RSV. We believe AT-889 or one of our other candidates for RSV has the potential to inhibit both initiation of viral replication, as well as viral transcription. We anticipate nominating our product candidate and initiating the IND-enabling studies in the second half of 2021. We believe that the product candidate we develop, if successful, could be the first therapy in over 30 years to be approved specifically for the treatment of RSV.

Financial Operations Overview

As of March 31, 2021, we had cash and cash equivalents of \$833.8 million. Net cash used in operating activities was \$16.8 million for the three months ended March 31, 2021. We expect that our net cash used in operating activities will increase significantly as we advance our product candidates through preclinical and clinical development, seek regulatory approval, and prepare for and, if approved, proceed to commercialization; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. In addition, we expect to incur additional costs as we continue to operate as a public company. We believe that our available cash and cash equivalents will be sufficient to fund our planned operations through at least 2023.

We do not have any product candidates approved for sale and have not generated any product revenue since inception. Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

We plan to continue to use third-party service providers, including contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”), to carry out our preclinical and clinical development and to manufacture and supply the materials to be used during the development and commercialization of our product candidates.

We expect to continue to incur significantly higher expenses over the next several years. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue clinical development of AT-527 for the treatment of COVID-19;
- continue clinical development of AT-752 for the treatment of dengue;
- re-initiate clinical development of AT-787 for the treatment of HCV;
- continue IND-enabling activities and commence clinical development activities for product candidates for the treatment of RSV;
- maintain, expand, protect and enforce our intellectual property portfolio;
- hire additional research, development and general and administrative personnel;
- establish commercialization capabilities; and
- incur additional costs associated with operating as a public company.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales. Our revenue has been collaboration revenue solely derived from the Roche License Agreement, which became effective in October 2020. If our development efforts for our product candidates are successful and result in commercialization, we may generate additional revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties.

Operating Expenses

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our product candidates. These expenses include fees paid to third parties, including CROs and CMOs, to conduct certain research and development activities on our behalf, consulting costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for our research and product development employees and allocated overhead, including rent, equipment, depreciation, information technology costs and utilities attributable to research and development personnel. We expense both internal and external research and development expenses as they are incurred. In circumstances where amounts have been paid in advance or in excess of costs incurred, we record a prepaid expense, which is expensed as services are performed or goods are delivered.

A significant portion of our research and development costs have been external costs, which we track by therapeutic area. Our internal research and development costs are primarily personnel-related costs, facility costs, including depreciation and lab consumables. We have not historically tracked our internal research and development expenses by therapeutic area as they are deployed across multiple programs.

As discussed in Note 3 to our unaudited consolidated financial statements, we and Roche share certain manufacturing and clinical development costs on a 50/50 basis. Billings to us by Roche for our percentage share of such expenses are recorded in research and development expenses. These costs represent a material portion of our total expenses and may continue to increase based on the activities being performed by Roche.

The following table summarizes our external research and development expenses by indication and internal research and development expenses:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
COVID-19 external costs	\$ 18,113	\$ 135
Dengue external costs	1,279	233
HCV external costs	15	1,441
RSV external costs	396	379
Internal research and development costs	6,768	633
Total research and development costs	\$ 26,571	\$ 2,821

We are focusing substantially all of our resources on the development of our product candidates, particularly AT-527. We expect our research and development expenses to increase substantially for at least the next few years, as we seek to initiate additional clinical trials for our product candidates, complete our clinical programs, pursue regulatory approval of our product candidates and prepare for the possible commercialization of these product candidates. Predicting the timing or cost to complete our clinical programs or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the U.S. Food and Drug Administration ("FDA") or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, allocated overhead, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with Nasdaq and SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Interest Income and Other, Net

Interest income and other, net, consists primarily of interest income earned on our cash and cash equivalents.

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended March 31,			Change
	2021	2020	(in thousands)	
Collaboration revenue	\$ 65,985	\$ —	\$ 65,985	
Operating expenses:				
Research and development	26,571	2,821	23,750	
General and administrative	8,759	1,224	7,535	
Total operating expenses	35,330	4,045	31,285	
Income (loss) from operations	30,655	(4,045)	34,700	
Interest income and other, net	58	57	1	
Net income (loss)	\$ 30,713	\$ (3,988)	\$ 34,701	

Revenue

Collaboration revenue for the three months ended March 31, 2021 was derived from the Roche License Agreement that was executed in October 2020. As discussed in Note 3 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, revenue is being recognized over the period in which the Company performs the Atea Ongoing Studies and the Atea Manufacturing Obligations.

Research and Development Expenses

Research and development expenses increased by \$23.8 million from \$2.8 million for the three months ended March 31, 2020 to \$26.6 million for the three months ended March 31, 2021. The increase in research and development expenses was primarily due to a \$17.5 million increase in external expenses incurred related to the CRO and CMO services in conjunction with the advancement of product candidates for the treatment of COVID-19 and dengue, including \$14.5 million related to the Company's share of costs incurred by Roche, and an increase of \$6.2 million in internal spend primarily due to an increase in personnel-related expenses, including salaries and bonuses, benefits and stock-based compensation expense of \$3.1 million for our research and product development employees and consulting fees and other research and development expenses. Research and development expenses include a reduction of \$3.4 million representing Roche's share of certain expenses incurred that are subject to ASC 808 as discussed in Note 3 to our unaudited consolidated financial statements. The Company also recorded research and development expense of \$14.5 million relating to its share of costs incurred by Roche.

General and Administrative Expenses

General and administrative expenses increased by \$7.6 million from \$1.2 million for the three months ended March 31, 2020 to \$8.8 million for the three months ended March 31, 2021. The increase in general and administrative expenses was primarily due to the expansion of our organization and reflected an increase in payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense of \$5.0 million; professional fees of \$1.0 million; and an increase in other general and administrative expenses of \$1.5 million.

Interest Income and Other, Net

Interest income and other, net, remained consistent during the three months ended March 31, 2021 compared to the three months ended March 31, 2020 primarily due to lower interest rates applied to higher investment balances.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2021, we had cash and cash equivalents of \$833.8 million. We believe that our available cash and cash equivalents will be sufficient to fund our planned operations through at least 2023.

Future Funding Requirements

To date, we have not generated any product revenue. We do not expect to generate any product revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates and we do not know when, or if, this will occur. We expect to continue to incur increased expenditures for the foreseeable future, and we expect our expenses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Moreover, we expect to incur additional general and administrative costs as we continue to operate as a public company.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through public or private equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. We anticipate that we may need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to maintain the collaboration with Roche and to establish and maintain other collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following regulatory approval;
- our implementation of operational, financial and management systems; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional 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 or 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.

Adequate 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. 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 or we may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

See Part II, Item 1A, "Risk Factors" for additional risks associated with our substantial capital requirements.

Summary Statement of Cash Flows

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

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (16,837)	\$ (4,508)
Investing activities	—	—
Financing activities	471	(6)
Net decrease in cash, cash equivalents and restricted cash	\$ (16,366)	\$ (4,514)

Cash Flows from Operating Activities

Net cash used in operating activities for the three months ended March 31, 2021 was \$16.8 million. Cash used in operating activities was primarily due to research and development expenses of \$26.6 million and general and administrative expenses of \$8.8 million, offset by stock-based compensation of \$7.3 million, an increase in accounts payable and accrued expenses of \$10.4 million, an increase in other assets of \$0.3 million and a decrease in prepaid expenses of \$1.2 million. The Company recognized revenue of \$66.0 million for the three months ended March 31, 2021. The revenue recognized did not have an impact on net cash used in operating activities as this amount was previously included in deferred revenue as of December 31, 2020.

Net cash used in operating activities was \$4.5 million for the three months ended March 31, 2020. Cash used in operating activities was primarily related to the use of funds in our efforts to develop our product candidates, resulting in a net loss of \$4.0 million, offset by stock-based compensation of \$0.2 million. Additional uses of cash during the period included an increase in prepaid expenses of \$0.2 million and a decrease in accounts payable and accrued expenses of \$0.5 million.

Cash Flows from Investing Activities

There were no cash flows from investing activities for either the three months ended March 31, 2021 or 2020.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$0.5 million for the three months ended March 31, 2021 and consisted of proceeds from the exercise of stock options.

Net cash used in financing activities was less than \$0.1 million for the three months ended March 31, 2020 and consisted of payments of deferred offering costs.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations during the three months ended March 31, 2021 from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

We enter into contracts in the normal course of business with third-party contract organizations including CROs and CMOs for preclinical and clinical studies and testing, manufacture and supply of our preclinical materials and other services and products used for operating purposes. These contracts do not contain any minimum purchase commitments and generally provide for termination following a certain period after notice, and therefore we believe that our non-cancelable obligations under these agreements are not material. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and 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. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies are described under the heading “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 for the year ended December 31, 2020. We believe that these accounting policies are critical to understanding our historical and future performance, as these policies relate to significant areas involving management’s judgments and estimates. During the three months ended March 31, 2021 there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K except as discussed in Note 2, “Summary of Significant Accounting Policies” in the financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

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

Indemnification Agreements

We enter into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, we indemnify, hold harmless and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, including in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments we could be required to make under these arrangements is not determinable. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the fair value of these agreements is minimal.

We have also agreed to indemnify our directors and officers for certain events or occurrences while the director or officer is, or was serving, at our request in such capacity. The indemnification period covers all pertinent events and occurrences during the director’s or officer’s service. The maximum potential amount of future payments we could be required to make under these indemnification agreements is not specified in the agreements; however, we have director and officer insurance coverage that reduces our exposure and enables us to recover a portion of any future amounts paid. We believe the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”) permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will not be subject to the same new or revised accounting standards as public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of our first fiscal year in which we have total annual revenues of more than \$1.07 billion; (2) the date we qualify as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) December 31, 2025.

Recent Accounting Pronouncements

See the section titled “Summary of Significant Accounting Policies—Recent Accounting Pronouncements” in Note 2 to our consolidated financial statements included in this Quarterly Report on Form 10-Q for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

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 and cash equivalents of \$833.8 million, consisting of interest-bearing money market funds for which the fair 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 cash equivalents, an immediate 10% relative change in interest rates would not have a material effect on the fair value of our cash equivalents or on our future interest income.

We do not believe that inflation, interest rate changes or foreign currency exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.

Limitations on effectiveness of controls and procedures

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.

Evaluation of disclosure controls and procedures

Our management, with the participation of our principal executive officer and principal 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 Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

Item 1. Legal Proceedings.

We are not subject to any material legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the risks and uncertainties described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and “Management’s Discussion and Analysis of Results of Operations and Financial Condition.” Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

Risks Related to COVID-19***There is significant uncertainty around our development of AT-527 as a potential treatment for COVID-19.***

Our development of AT-527 for the treatment of COVID-19 is in its early stages, and we may not be successful in our development of AT-527 as a potential treatment for COVID-19. In October 2020, we entered into a license agreement (“Roche License Agreement”) with F. Hoffmann-LaRoche Ltd. and Genentech, Inc. (together, “Roche”) under which we granted to Roche an exclusive license to development and commercialization rights related to certain of our compounds, including AT-527, outside of the United States (other than for certain HCV uses). Together with Roche, we have only recently initiated a Phase 3 clinical trial to study AT-527 in adult patients with mild or moderate COVID-19 in the outpatient setting. Concurrently, we are also evaluating AT-527 for the treatment of patients with mild to moderate COVID-19 in two Phase 2 clinical trials. Additionally, we are currently conducting a comprehensive Phase 1 program that includes one completed trial for which results were recently published, ongoing Phase 1 studies and additional Phase 1 studies that are being planned. We have committed and plan to continue to commit significant financial and personnel resources to the development of AT-527 as a potential treatment for COVID-19. If we are unable to successfully develop AT-527 for the treatment of COVID-19, we will have taken resources away from other development programs and will not be able to recuperate the resources dedicated to developing AT-527 as a potential treatment for COVID-19, which could have a material adverse impact on our business. If the data from our clinical trials are not supportive of further development of AT-527 as a treatment for COVID-19 or the investor community has a negative reaction to the data, the demand for our common stock could decrease significantly, and the price of our common stock could decline substantially, which could result in significant losses for our stockholders.

Further, while there is currently an urgent need for a treatment for COVID-19, the longevity and extent of the ongoing COVID-19 pandemic is uncertain and it is unclear whether SARS-CoV-2 will become an endemic human coronavirus that may circulate in the human population after the current pandemic has subsided. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability of vaccines, or otherwise, the need for a treatment could decrease significantly. If the need for a treatment decreases before or soon after commercialization of AT-527, if approved, or other treatments for COVID-19 are developed before AT-527, our business could be adversely impacted.

We may expend resources in anticipation of clinical trials and potential commercialization of AT-527, which we may not be able to recover if AT-527 is not approved for the treatment of COVID-19 or we are not successful at commercializing AT-527.

We believe that there is an urgent unmet need for effective orally administered COVID-19 treatments particularly for patients in the outpatient setting. Accordingly, if the data from our ongoing and planned clinical trials of AT-527 in COVID-19 patients are positive, we may pursue certain expedited development, review and approval programs offered by the U.S. Food and Drug Administration (“FDA”) to sponsors of drugs designed to treat serious diseases and conditions. These programs may offer the potential for a more rapid approval and commercialization process than traditional FDA review pathways. In order to prepare for the possibility that we may be required to develop and rapidly commercialize AT-527, we have entered and may enter into additional agreements with, and make payments to, contract manufacturing organizations (“CMOs”), third parties we are engaging to assist us in the potential commercialization of AT-527, and other third parties prior to obtaining any approval to market AT-527 for the treatment of COVID-19. As a result, we may not be able to recover these costs if AT-527 is not approved for the treatment of COVID-19, which could have a material adverse effect on our business.

We currently expect that the market for a treatment for COVID-19 will be large, and we cannot be certain that Roche, our exclusive supplier of AT-527 commercial product for COVID-19, will be able to satisfy commercial demand for AT-527, if approved. If AT-527 is approved and we are unable to meet commercial demand, we may not be able to fully capitalize on our development of AT-527, which could have an adverse effect on our business.

Furthermore, we have never commercialized a product and may not be successful in establishing the capabilities required for commercialization. In order to commercialize AT-527, we are developing commercial capabilities. If we do not obtain approval for AT-527, we will have expended those resources prematurely, and our business could be adversely affected.

There has also been significant media coverage regarding the pricing of any vaccine or treatment for COVID-19. For example, Gilead Sciences, Inc. came under scrutiny regarding its pricing of Veklury (remdesivir), after having donated the initial supply of the drug. Pricing for drugs to treat COVID-19 continues to evolve, and we cannot be certain of the factors that will determine the sales price of AT-527, if approved. If we are unable to sell AT-527 at a sufficient price point, our ability to commercialize AT-527, if approved, may be adversely affected.

AT-527 may face significant competition from vaccines and other treatments for COVID-19 that are in development.

Many biotechnology and pharmaceutical companies are developing treatments for COVID-19 or vaccines against SARS-CoV-2, the virus that causes COVID-19. Many of these companies, which include large pharmaceutical companies, have greater resources for development and established commercialization capabilities. For example, in October 2020, the FDA approved the antiviral drug Veklury (remdesivir), a direct acting antiviral marketed by Gilead Sciences for the treatment of COVID-19 for certain patients requiring hospitalization and in November 2020 the FDA granted Regeneron an emergency use authorization for the use of casirivimab and imdevimab, administered together, for the treatment of mild to moderate coronavirus COVID-19 in adult and certain pediatric patients with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19 and/or hospitalization. In the same month, FDA granted Eli Lilly emergency use authorization for bamlanivimab for the treatment of mild to moderate COVID-19 in adult and certain pediatric patients. There are other companies that are currently pursuing authorization for emergency use of their respective products. For example, in March 2021, VIR Biotechnology, Inc. and GlaxoSmithKline submitted to the FDA a request for authorization for the emergency use of VIR-7831 for the treatment of adults and adolescents with mild to moderate COVID-19. In addition to therapeutics, vaccines indicated for active immunization to prevent COVID-19 have been recently authorized for emergency use. In December 2020, the FDA granted authorization for emergency use for vaccines from Pfizer Inc. and BioNTech and Moderna, Inc. each of which announced clinical trial results showing that their respective vaccine candidate was found to be more than 90% effective in preventing COVID-19 during such trials and in February 2021, the FDA granted emergency use authorization to a vaccine developed by Janssen Pharmaceutical Company. Additional vaccines and therapeutics are in development by other pharmaceutical and biopharmaceutical companies. For example, molnupiravir, an orally administered direct-acting antiviral, which is being developed by Merck and Ridgeback Biotherapeutics is currently in Phase 2/3 development in the outpatient setting and Pfizer has initiated clinical development of protease inhibitors, another form of direct acting antiviral. Given the products currently approved or authorized for use as well as those in development by others, any treatment we may develop could face significant competition. If any other company develops treatments more rapidly or effectively than we do, develops a treatment that becomes the standard of care, develops a treatment at a lower cost, or is more successful at commercializing an approved treatment, we may not be able to successfully commercialize AT-527 for the treatment of COVID-19, even if approved, or compete with other treatments or vaccines, which could adversely impact our business and operations.

The COVID-19 pandemic may materially and adversely affect our business and financial results.

In December 2019, SARS-CoV-2 surfaced in China. Since then, COVID-19 has spread globally. In the United States, travel bans and government stay-at-home orders caused widespread disruption in business operations and economic activity. Governmental authorities around the world implemented measures to reduce the spread of COVID-19. These measures, including suggested or mandated “shelter-in-place” orders, have adversely affected workforces, customers, consumer sentiment, economies, and financial markets, and, along with decreased consumer spending, have contributed to an economic downturn in the United States. In response to the public health directives and orders and to help minimize the risk of COVID-19 for our employees, we have taken precautionary measures, including implementing work-from-home policies for all our employees. Many of our third-party collaborators, such as our CMOs, clinical research organizations (“CROs”), suppliers and others, have taken similar precautionary measures. These measures have disrupted our business and delayed certain of our clinical programs and timelines. For example, our Phase 1/2a clinical trial of AT-787 for the treatment of hepatitis C virus (“HCV”) was paused when clinical trial sites closed due to COVID-19 precautions by the countries and medical facilities where the trial was to be conducted. As certain countries have reopened, they have experienced a new surge of infection and have in some areas reinstated stay at home and other containment measures.

Efforts to re-open are likely to take a significant amount of time, require additional resources to implement social-distancing and other containment measures, or may not be successful.

The impact to our operations due to the COVID-19 pandemic could be severe and could negatively affect our business, financial condition and results of operations. 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 risk factors described in this "Risk Factors" section, such as those relating to our clinical trial timelines, our ability to enroll subjects for clinical trials and obtain materials that are required for the production of our product candidates, and our ability to raise capital.

The COVID-19 pandemic may materially and adversely affect our clinical trials.

As a result of the COVID-19 pandemic, we may experience additional disruptions that could severely impact our clinical trials, including:

- delays or difficulties in enrolling patients in a clinical trial, including rapidly evolving treatment paradigms, and patients that may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators, and clinical site staff, or the overwork of existing investigators and staff;
- diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or provincial governments, employers and others;
- the risk that participants enrolled in our non-COVID-19-related clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product;
- changes in local regulations as part of a response to the COVID-19 outbreak that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- the refusal of the FDA to accept data from clinical trials in these affected geographies.

For example, our HCV program was delayed when clinical trial sites conducting our Phase 1/2a trials closed, and our other development programs may be delayed or otherwise negatively impacted. As a result, the expected timeline for data readouts of our clinical trials and certain regulatory submissions will likely be negatively impacted, which would adversely affect and delay our ability to seek regulatory approvals for our product candidates, increase our operating expenses, and have a material adverse effect on our financial condition. Moreover, SARS-CoV-2 is a novel pathogen, and information regarding the emergence of viral variants, and the symptoms, progression, and transmission of COVID-19 continues to rapidly evolve, which may present additional challenges for the conduct of our clinical trials in COVID-19 patients. For example, COVID-19 patients have presented with a wide range of symptoms and side effects, which may make it more difficult for clinical trial investigators to determine whether any adverse events observed in our clinical trials are related to AT-527 or are consistent with the underlying disease. Any increase in the severity or incidence of adverse events deemed to be

related to AT-527 could delay or prevent its regulatory approval, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history and no history of successfully developing or commercializing any approved antiviral products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability.

We are a clinical-stage biopharmaceutical company. Our operations to date have been limited to financing and staffing our company, developing our technology and identifying and developing our product candidates. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by biopharmaceutical companies in their early stages of operations. We have not yet demonstrated an ability to complete any late-stage or pivotal clinical trials, obtain marketing approval, manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization, or arrange for third parties to do these activities on our behalf. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing antiviral therapies.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. If we successfully develop a product candidate, we will eventually need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in this transition. For example, we may need to rapidly develop our commercialization capabilities if AT-527 is approved for the treatment of COVID-19.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance.

We have incurred significant operating expenses since inception and expect to incur significant additional operating expenses for the foreseeable future. We have no products that have generated any commercial revenue and we may not maintain profitability.

We have incurred significant operating expenses since our inception, including operating expenses of \$35.3 million and \$59.7 million for the three months ended March 31, 2021 and the year ended December 31, 2020, respectively. Prior to the quarter ended March 31, 2021, we had incurred significant operating losses. In addition, we have not commercialized any products and have never generated any revenue from product sales. We have devoted almost all of our financial resources to research and development, including our clinical trials and preclinical development activities.

We expect to continue to incur significant additional operating expenses for the foreseeable future as we seek to advance product candidates through clinical development, continue preclinical development, expand our research and development activities, develop new product candidates, complete preclinical studies and clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products, and we may incur operating losses in future periods. In order to obtain FDA approval to market any product candidate in the United States, we must submit to the FDA a New Drug Application ("NDA") demonstrating to the FDA's satisfaction that the product candidate is safe and effective for its intended use(s). This demonstration requires significant research and extensive data from animal tests, which are referred to as nonclinical or preclinical studies, as well as human tests, which are referred to as clinical trials. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial and difficult to accurately predict. Because of the numerous risks and uncertainties associated with the development of drug products, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or maintain profitability. Our expenses will also increase substantially if or as we:

- initiate additional clinical trials of our most advanced product candidate, AT-527, and progress our ongoing clinical trials for the treatment of patients with moderate COVID-19 and our current and planned Phase 1 clinical trials in healthy volunteers;
- advance the development of our other product candidates, including resuming our Phase 1/2a clinical trial of AT-787 for the treatment of HCV, which has been delayed due to the COVID-19 pandemic, and a Phase 1 clinical trial of AT-752 for the treatment of dengue, and the preclinical development of our other product candidates, including AT-899 and other product candidates for the treatment of RSV;

- continue to discover and develop additional product candidates;
- seek regulatory and marketing approvals for product candidates that successfully complete clinical trials, if any;
- establish manufacturing and supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain marketing approval, if any;
- establish a sales, marketing, internal systems and distribution infrastructure to commercialize any products for which we may obtain regulatory approval, if any, in geographies in which we plan to commercialize our products ourselves or with co-promotion collaborators;
- maintain, expand, protect and enforce our intellectual property portfolio;
- hire additional staff, including clinical, scientific, technical, regulatory, operational, financial, commercial and support personnel, to execute our business plan and support our product development and potential future commercialization efforts;
- more extensively utilize external vendors for support with respect to research, development, manufacturing, commercialization, regulatory, pharmacovigilance and other functions;
- acquire or in-license commercial products, additional product candidates and technologies;
- make royalty, milestone or other payments under any future in-license agreements; and
- incur additional legal, accounting and other expenses in operating our business as a public company.

Furthermore, our ability to successfully develop, commercialize and license any products and generate product revenue is subject to substantial additional risks and uncertainties. Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in not less than one jurisdiction, the securing of manufacturing supply, capacity, distribution channels and expertise, the use of external vendors, the building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. As a result, we expect to continue to incur operating expenses and use cash for operating activities for the foreseeable future. These operating expenses and use of cash have had, and will continue to have, an adverse effect on our working capital. Additionally, we may incur operating losses in future periods.

The amount of future expenses or losses and our ability to maintain profitability are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products in the foreseeable future until we have successfully developed one or more product candidates, and might never generate revenues from the sale of products. Our ability to generate product revenue and maintain profitability will depend on, among other things, successful completion of the clinical development of our product candidates; obtaining necessary regulatory approvals from the FDA and foreign regulatory authorities; establishing manufacturing and sales capabilities; market acceptance of our products, if approved, and establishing marketing infrastructure to commercialize our product candidates for which we obtain approval; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

We will require substantial additional financing, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have incurred substantial expenses since inception. We expect to continue to incur substantial expenses to continue the clinical development of AT-527, AT-752 and AT-787, for future clinical trials for our other product candidates and to continue to identify new product candidates.

We will continue to need additional capital to fund future clinical trials and preclinical development, which we may raise through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. Additional sources of financing might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we might be unable to initiate or complete planned clinical trials or seek regulatory approvals of any of our product candidates from the FDA, or any foreign regulatory authorities, and could be forced to discontinue product development. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

Based on our current operating plan, we believe that our cash and cash equivalents as of March 31, 2021, will be sufficient to fund our operating expenses and capital expenditure requirements through at least 2023. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We will require significant additional funds in order to launch and commercialize our current and any future product candidates to the extent that such launch and commercialization are not the responsibility of a collaborator. In addition, other unanticipated costs may arise in the course of our development efforts. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of our preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for our current and future product candidates in regions where we choose to commercialize any products;
- the number of future product candidates and potential additional indications that we may pursue and their development requirements;
- the stability, scale, yield and cost of manufacturing our product candidates for clinical trials, in preparation for regulatory approval and in preparation for commercialization;
- the costs of commercialization activities for any approved product candidate to the extent such costs are not the responsibility of any collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs and timing of changes in pharmaceutical pricing and reimbursement infrastructure;
- subject to receipt of regulatory approval and revenue, if any, received from commercial sales for any approved indications for any of our product candidates;
- our ability to compete with other therapies in the indications we target;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property-related claims; and
- the costs of operating as a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts, on terms acceptable to us, or on a timely basis, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives.

We have not generated any revenue from product sales and may not be able to maintain profitability.

Our ability to maintain profitability depends upon our ability to generate revenue from product sales. Prior to the execution of the Roche License Agreement, we had not generated any revenue and do not expect to generate product revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. Our product candidates are in varying stages of development which may necessitate additional preclinical studies in some cases and in all cases will require additional clinical development as well as regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely initiation and completion of our clinical trials of AT-527, AT-787 and AT-752, our preclinical studies and our future clinical trials, which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;

- our ability to complete additional investigational new drug application (“IND”), enabling studies and successfully submit INDs or comparable applications to allow us to initiate clinical trials for our product candidates;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities the safety and efficacy of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA or similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates as potential antiviral therapies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (“cGMP”);
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; and
- our ability to establish, maintain, protect and enforce intellectual property rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control, and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, we may not be able to maintain profitability after generating product sales. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

Our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income may be subject to certain limitations.

As of December 31, 2020, we had U.S. federal net operating loss carryforwards (“NOLs”), of \$53.2 million, which may be available to offset future taxable income, if any, of which \$27.5 million begin to expire in 2033 and of which \$25.7 million do not expire but are limited in their usage (for taxable years beginning after December 31, 2020) to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2020, we had state NOLs of \$52.5 million, which may be available to offset future taxable income, if any, and begin to expire in 2033. As of December 31, 2020, we also had federal and state research and development credit carryforwards of \$1.6 million and \$0.3 million, respectively, which begin to expire in 2033. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the “Code”), a corporation that undergoes an “ownership change,” generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Sections 382 and 383 of the Code. For these reasons, we may not be able to utilize a material portion of the NOLs or research and development credit carryforwards even if we attain profitability.

Risks Related to the Discovery, Development, Preclinical and Clinical Testing, Manufacturing and Regulatory Approval of Our Product Candidates

Our business is highly dependent on the success of our most advanced product candidates, particularly AT-527, each of which will require significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales. If these product candidates fail in clinical development, do not receive regulatory approval or are not successfully commercialized, or are significantly delayed in doing so, our business will be harmed.

A substantial portion of our business and future success depends on our ability to develop, obtain regulatory approval for and successfully commercialize our most advanced product candidates, AT-527 for the treatment of COVID-19, AT-787 for the treatment of HCV, and AT-752 for the treatment of dengue fever. We currently have no products that are approved for commercial sale and have not completed the development of any of our product candidates, and we may never be able to develop marketable products. Other than our development of AT-527 for the treatment of COVID-19, for which we expect to expend resources in the near term, we expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our most advanced product candidates, which will require additional clinical development, management of clinical, medical affairs and manufacturing activities, obtaining regulatory approvals in multiple jurisdictions, securing of manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we can generate any revenues from any commercial sales from any product candidate, if approved. We cannot be certain that any of our product candidates will be successful in clinical trials, receive regulatory approval or be successfully commercialized even if we receive regulatory approval. Further, our development of any product candidate may be delayed, which may affect our ability to successfully commercialize such product. For example, enrollment in our Phase 1/2a trial of AT-787 for the treatment of HCV has been delayed due to the COVID-19 pandemic. Additionally, if our competitors develop products to treat COVID-19, HCV, RSV, dengue, or any other diseases which our current or future product candidates are being developed to treat, before we are able to successfully develop a product candidate, or if our competitors develop any products that are superior to our product candidates, our potential market share could become smaller or non-existent. Even if we receive approval to market these product candidates from the FDA or other regulatory bodies, we cannot be certain that our product candidates will be as or more effective than other commercially available alternatives, successfully commercialized or widely accepted in the marketplace. Nor can we be certain that, if approved, the safety and efficacy profile of our product candidates will be consistent with the results observed in clinical trials. If we are not successful in the clinical development of our most advanced product candidates, the required regulatory approvals for these product candidates are not obtained, there are significant delays in the development or approval of these product candidates, or any approved products are not commercially successful, our business, financial condition and results of operations may be materially harmed.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, expensive, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be seriously harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA 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. Although we believe that our ongoing and planned Phase 2 and Phase 3 clinical trials of AT-527 in patients with mild or moderate COVID-19, if successful, may enable us to submit an NDA seeking approval of AT-527 for the treatment of mild or moderate COVID-19, there is no guarantee that the FDA will agree with any strategy we may propose. We have not submitted an NDA for, or obtained regulatory approval of, any product candidate. We must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the regulatory authorities before we will be able to obtain these approvals, 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 for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or interpretation of results of our clinical trials;
- the FDA 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 obtaining marketing approval or prevent or limit commercial use of our products;
- 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 or comparable foreign regulatory authorities that a product candidate's clinical and other benefits outweigh its safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' 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 seriously harm our business. In addition, even if we or our collaborators were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy ("REMS"). Regulatory authorities may not approve the price we or our collaborators intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

Clinical development is lengthy and uncertain. We may encounter substantial delays and costs in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Before obtaining marketing approval from the FDA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, time-consuming and subject to uncertainty. A failure of one or more clinical trials can occur at any stage of the process, and the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. To date, we have not completed any late-stage or pivotal clinical trials for any of our product candidates. We cannot guarantee that any of our planned or ongoing clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of any future IND or similar application will result in the FDA or other regulatory authority, as applicable, allowing future clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of 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 reaching a consensus with regulatory authorities on study design or implementation of the clinical trials;
- delays or failure in obtaining regulatory authorization to commence a trial;

- 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 CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required institutional review board (“IRB”) or ethics committee, approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an IND or amendment or equivalent foreign application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; or a negative finding from an inspection of our clinical trial operations or study sites;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up, including due to the COVID-19 pandemic;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA’s or any other regulatory authority’s good clinical practice requirements (“GCPs”), or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- changes to the clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- 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;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- 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 development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a CMO and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. For example, due to the COVID-19 pandemic, our Phase 1/2a clinical trial of AT-787 for the treatment of HCV was paused until our clinical sites are able to re-open and we elect to resume enrollment, which has not yet occurred. Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue from product sales. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our

modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which any approved 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 seriously harm our business.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board (“DSMB”), for such trial, or by the FDA or any other regulatory authority, or if the IRBs or ethics committees 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 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.

Further, conducting clinical trials in foreign countries, as we are doing for our COVID-19 and dengue product candidates, and as we expect to resume for our HCV product candidate, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

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

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

Our product candidates may be associated with serious adverse events, 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, our collaborators, any DSMB for a trial, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval.

If any serious adverse events occur, clinical trials or commercial distribution of any product candidates or products we develop could be suspended or terminated, and our business could be seriously harmed. Treatment-related

side effects could also affect patient recruitment and the ability of enrolled patients to complete the trial or result in potential liability claims. Regulatory authorities could order us to cease further development of, deny approval of, or require us to cease selling any product candidates or products for any or all targeted indications. If we are required to delay, suspend or terminate any clinical trial or commercialization efforts, the commercial prospects of such product candidates or products may be harmed, and our ability to generate product revenues from them or other product candidates that we develop may be delayed or eliminated. 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 suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- 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 seriously harm our business, financial condition and results of operations.

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

We may develop future product candidates in combination with other product candidates or existing therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used in antiviral treatments, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than currently anticipated. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell the product candidates we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market the product candidates we develop.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. 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. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the target disease population;
- the size of the patient population required for analysis of the trial's primary endpoints;

- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before trial completion; and
- other factors outside of our control, such as the COVID-19 pandemic which has, among other things, created substantial burdens on healthcare providers who may be required to prioritize immediate critical patient care over clinical research.

For example, due to the COVID-19 pandemic, our Phase 1/2a trial of AT-787 for the treatment of HCV was paused until our clinical sites are able to re-open and we elect to resume enrollment, which has not yet occurred. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates or similar areas, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates.

We currently conduct clinical trials, and may in the future choose to conduct additional clinical trials, of our product candidates in sites outside the United States, and the FDA may not accept data from trials conducted in foreign locations.

We currently conduct, and may in the future choose to conduct, clinical trials outside the United States for our product candidates. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be conducted in accordance with GCP, and the FDA must also be able to validate the data from the study through an on-site inspection if necessary. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for which we intend to seek approval for the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, the FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our clinical trials of our product candidates, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

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

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Consequently, the top-line or preliminary data that we report may differ from final results reported from the same studies, or different conclusions or considerations may qualify such preliminary or topline data, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final results being materially different from the preliminary or topline data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

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

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

We may not be successful in our efforts to identify and successfully develop additional product candidates.

Part of our strategy involves identifying novel product candidates. The process by which we identify novel product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third-parties' patent or other intellectual property or exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance, if approved;
- potential product candidates may not be effective in treating their targeted diseases or symptoms;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically.

If we are unable to identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

We may focus on potential product candidates that may prove to be unsuccessful and we may have to forego opportunities to develop other product candidates that may prove to be more successful.

We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential.

Furthermore, we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidates, particularly AT-527, and as such, we may forgo or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate, we may relinquish valuable rights to those future product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates.

A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a Breakthrough Therapy designation for our product candidates if the clinical data support such a designation for one or more product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, 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 product candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs designated as Breakthrough Therapies by the FDA may also be eligible for priority review, if the relevant criteria are met.

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

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

We are developing certain product candidates for the treatment of serious and life-threatening conditions, including AT-527 for the treatment of COVID-19, and therefore may decide to seek approval of such product candidates under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If the sponsor fails to conduct such studies in a timely manner, or if such post-approval studies fail to verify the drug's predicted clinical benefit, the FDA may withdraw its approval of the drug on an expedited basis.

If we decide to submit an NDA seeking accelerated approval or receive an expedited regulatory designation for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate would result in a longer time period to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate, which could harm our competitive position in the marketplace.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of any product candidate we develop.

Any product candidates we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. Our development programs are early-stage and we have not received approval to market any product candidates from regulatory authorities in any jurisdiction. It is possible that none of the product candidates we are developing or that we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs, suppliers, vendors or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if numerous clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries 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. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate product revenue will be materially impaired.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current approved antiviral products are well established in the medical community for the treatment of HCV, and doctors may continue to rely on these therapies. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- adoption of a companion diagnostic and/or complementary diagnostic; and
- the prevalence and severity of any side effects.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the

categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

Though we have insurance coverage for clinical trial product liability, we do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, property, auto, workers' compensation, umbrella, and directors' and officers' insurance.

Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future 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. If we obtain marketing approval for any of our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. 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.

Operating as a public company has and will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash and cash equivalents position and results of operations.

Our business and operations would suffer in the event of system failures, deficiencies or intrusions.

Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to failure or damage from computer viruses and other malware, unauthorized access or other cybersecurity attacks, natural disasters (including hurricanes), terrorism, war, fire and telecommunication or electrical failures. In the ordinary course of our business, we directly or indirectly collect, store and transmit sensitive data, including intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data and personally identifiable health information of our clinical trial subjects and employees, in our data centers and on our networks, or on those of third parties. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, level of persistence, intensity and sophistication of attempted attacks and intrusions from around the world have increased. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cybercriminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Because of this, we may also experience security breaches that may remain undetected for an extended period. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages or breaches in our systems or those of our CROs and other contractors and consultants.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical studies or clinical trial data from completed, ongoing or planned studies or trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen.

Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and such an event could disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

We will be subject to extensive and costly government regulation.

Our product candidates will be subject to extensive and rigorous domestic government regulation, including regulation by the FDA, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective equivalents outside of the United States. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import and export of pharmaceutical products. If our products are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling our products. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. We must obtain and maintain regulatory authorization to conduct preclinical studies and clinical trials. We must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive preclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product's safety

and efficacy, potency and purity, for each intended use. The development and approval process takes many years, requires substantial resources, and may never lead to the approval of a product.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our consultants, CMOs, CROs or other vendors, fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things, delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and/or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

Enacted and future healthcare legislation and policies may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and could adversely affect our business.

In the United States, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could prevent or delay marketing approval of our products in development, restrict or regulate post-approval activities involving any product candidates for which we obtain marketing approval, impact pricing and reimbursement and impact our ability to sell any such products profitably. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted.

In March 2010, the Patient Protection and Affordable Care Act (“ACA”), was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer’s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer’s Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. By way of example, in 2017, the Tax Cuts and Jobs Act (“the Tax Act”) was signed into law, which included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. On December 14, 2018, the U.S. District Court for the Northern District of Texas ruled that the ACA is unconstitutional in its entirety because the penalty imposed by the individual mandate, which was deemed an integral part of the ACA, was reduced to \$0 and effectively nullified by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, although it remains unclear how and when the Supreme Court will rule. On June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued that these payments were owed to them. This was appealed to the Supreme Court, who reversed the Federal Circuit’s decision on April 27, 2020, and ruled that the government must make risk corridor payments. It is unclear how other efforts to challenge, repeal or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011 included aggregate reductions of Medicare payments to providers of 2% per fiscal year, effective April 1, 2013 which, due to subsequent legislative amendments, will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as outcomes-based reimbursement. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States and the EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny and post-marketing requirements.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if one of our product candidates is approved, it 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 FDA and comparable foreign regulatory authority requirements, 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 approved marketing application. 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.

If the FDA or another regulatory authority 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 authorities 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 authority or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our 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; or
- 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 adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business will be seriously harmed.

Moreover, the policies of the FDA and of other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which makes it illegal for any person to knowingly and willfully solicit, offer, receive, pay or provide any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, 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 U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act (the "FCA"), which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false, fictitious or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Companies that submit claims directly to payors may also be liable under the FCA for the direct submission of such claims. 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 FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should

know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), and its implementing regulations, which created additional 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. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal Food, Drug and Cosmetic Act ("FDCA"), which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers starting in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where reported prices may be used in the calculation of reimbursement and/or discounts on approved products;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private 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 U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock or stock options for services provided to us and may be in the position to influence the ordering of or use of our product candidates, if approved, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-

consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA, and, in the EU, Regulation 2016/679, known as the General Data Protection Regulation (the "GDPR"). New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. For example, on June 28, 2018, California enacted the California Consumer Privacy Act (the "CCPA"), which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers, increases the privacy and security obligations of entities handling certain personal information, requires new disclosures to California individuals and affording such individuals new abilities to opt out of certain sales of personal information, and provides for civil penalties for violations as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act ("CPRA") recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our CROs or business associates or another third party, could adversely affect our business, financial condition and results of operations, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief.

The privacy laws in the EU have been significantly reformed in recent years. On May 25, 2018, the GDPR entered into force and became directly applicable in all EU member states. The GDPR and related implementing laws in individual EU Member States govern the collection and use of personal health data and other personal data in the EU including the personal data processed by companies outside the EU in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior (including in the context of clinical trials). The GDPR rules are also applicable in the European Economic Area ("EEA"), which consists of the 27 EU Member States plus Norway, Liechtenstein and Iceland. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for collecting and processing personal data, requires the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance, including policies, procedures, training and data audit. The GDPR provides that EU member states may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union.

In addition, from January 1, 2021, we are subject to the GDPR and also the United Kingdom (“U.K.”) GDPR (“U.K. GDPR”), which, together with the amended U.K. Data Protection Act 2018, retains the GDPR in U.K. national law. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how U.K. data protection laws and regulations will develop in the medium to longer term, and for example how data transfers to and from the U.K. will be regulated in the long term, which exposes us to further compliance risk. These changes will lead to additional costs and increase and expose us to two parallel regimes each with the power to fine up to the greater of either €20 million (for the EU) or £17,500,000 (for the U.K.), or 4% of global turnover for violations. Currently there is a four to six-month grace period agreed in the EU and U.K. Trade and Cooperation Agreement, ending June 30, 2021 at the latest, while the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from EU member states to the U.K. for a four-year period, subject to subsequent extensions. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition.

We cannot assure you that our CROs or other third-party service providers with access to our or our customers’, suppliers’, trial patients’ and employees’ personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, use, storage and transmission of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers in the US, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA’s criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA’s requirements for disclosure of individually identifiable health information. Even when HIPAA does not apply, according to the Federal Trade Commission (the “FTC”), failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations. As such, we may be subject to state laws, requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the U.K. GDPR, GDPR and legislation of the EU member states implementing it.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our CROs and other third-party contractors to comply with the strict rules on the transfer of personal data outside of the EU into the United States may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals’ health information.

Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the

information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory privacy requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with applicable laws and regulations, our policies and other legal or contractual requirements, which may give rise to regulatory enforcement action, liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our common stock.

Risks Related to Commercialization

Developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets.

Our industry has been characterized by extensive research and development efforts, rapid developments in technologies, intense competition and a strong emphasis on proprietary products. We expect our product candidates to face intense and increasing competition as new products enter the relevant markets and advanced technologies become available. We face potential competition from many different sources, including pharmaceutical, biotechnology and specialty pharmaceutical companies. Academic research institutions, governmental agencies and public and private institutions are also potential sources of competitive products and technologies. Our competitors may have or may develop superior technologies or approaches, which may provide them with competitive advantages. Many of these competitors may also have compounds already approved or in development in the therapeutic categories that we are targeting with our product candidates. In addition, many of these competitors, either alone or together with their collaborative partners, may operate larger research and development programs or have substantially greater financial resources than we do, as well as greater experience in:

- developing product candidates;

- undertaking preclinical testing and clinical trials;
- obtaining NDA approval by the FDA;
- comparable foreign regulatory approvals of product candidates;
- formulating and manufacturing products; and
- launching, marketing and selling products.

If these competitors access the marketplace before we do with safer, more effective, or less expensive therapeutics, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals and manufacturing and selling commercial quantities of potential products.

Significant competition exists from approved treatments or treatments in development for the diseases that we are targeting. Many of the approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. There are pharmaceutical and biotechnology companies at various stages of development and approval of treatments for COVID-19 (or vaccines for SARS-CoV-2), HCV, dengue and RSV. There are several vaccines and drugs authorized for emergency use and one drug approved for the treatment of certain patients with COVID-19 requiring hospitalization, several drugs approved for the treatment of HCV, an approved vaccine for dengue and an approved drug for the treatment of RSV. Our product candidates are intended to compete directly or indirectly with existing products and products currently in development. Even if approved and commercialized, our product candidates may fail to achieve market acceptance with hospitals, physicians or patients. Hospitals, physicians or patients may conclude that our products are less safe or effective or otherwise less attractive than existing drugs. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable.

Many of our competitors have substantially greater capital resources, robust product candidate pipelines, established presence in the market and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. As a result, our competitors may achieve product commercialization or patent or other intellectual property protection earlier than we can. 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 clinical, regulatory, scientific, sales, marketing 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 programs. 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 or that would render any products that we may develop obsolete or noncompetitive.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs and biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare program is increasingly used as a model for how private and other governmental payors develop their coverage and reimbursement policies for new drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Some third-party payors may require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in the EU and other jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing any of our product candidates, if approved, and we may not be able to generate any product revenue.

We have limited personnel or infrastructure for the sales, marketing or distribution of products, and no experience as a company in commercializing a product candidate. The cost of building and maintaining such an organization may exceed the cost-effectiveness of doing so.

We may build our own focused sales, distribution and marketing infrastructure to market our product candidates, if approved, in the United States and other markets around the world. There are significant expenses and risks involved with building our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any

failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of our product candidate, if approved. Additionally, if the commercial launch of our product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our future products;
- our inability to equip medical and sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding applicable diseases and our future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to develop or obtain sufficient operational functions to support our commercial activities; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, or decide not to do so for a particular country, we may pursue collaborative arrangements. If we pursue a collaborative arrangement, our sales will largely depend on the collaborator's strategic interest in the product and such collaborator's ability to successfully commercialize the product. For example, we have an option to request Roche co-promote with us AT-527 for the treatment of COVID-19 in the U.S. If we elect to exercise this option, we will be dependent in part on Roche's efforts to successfully co-promote this product with us.

If we are unable to build our own sales force or access a collaborative relationship for the commercialization of any of our product candidates, we may be forced to delay the potential commercialization of our product candidates or reduce the scope of our sales or marketing activities for such product candidates. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to any of our product candidates or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our other product candidates and may not become profitable and may incur significant additional losses. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

In addition, even if we do establish adequate sales, marketing and distribution capabilities, the progress of general industry trends with respect to pricing models, supply chains and delivery mechanisms, among other things, could deviate from our expectations. If these or other industry trends change in a manner which we do not anticipate or for which we are not prepared, we may not be successful in commercializing our product candidates or become profitable.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. For example, we will depend on Roche to commercialize AT-527 for the treatment of COVID-19 in markets outside the U.S. We are evaluating the opportunities for the development and commercialization of our other product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries, we may be required to

comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities if we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- our ability to supply our product candidates on a timely and large-scale basis in local markets;
- longer lead times for shipping which may necessitate local manufacture of our product candidates;
- language barriers for technical training and the need for language translations;
- reduced protection of patent and other intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

If any of our product candidates is approved for commercialization, we may selectively partner with third parties to market it in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries, including requirements specific to biologics or cell therapy products;
- reduced protection for patent and other intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the EU and many of the individual member states in Europe with which we will need to comply. Many U.S.-based biotechnology companies have found the process of marketing their own products in Europe to be very challenging.

Certain legal and political risks are also inherent in foreign operations. There is a risk that foreign governments may nationalize private enterprises in certain countries where we may operate. In certain countries or regions, terrorist activities and the response to such activities may threaten our operations more than in the United States. Social and cultural norms in certain countries may not support compliance with our corporate policies, including those that require compliance with substantive laws and regulations. Also, changes in general economic and political conditions in countries where we may operate are a risk to our financial performance and future growth. Additionally, the need to identify financially and commercially strong partners for commercialization outside the United States who will comply with the high manufacturing and legal and regulatory compliance standards we require is a risk to our financial performance. As we operate our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other related risks. There can be no assurance

that the consequences of these and other factors relating to our international operations will not have an adverse effect on our business, financial condition or results of operations.

In some countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

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

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs, which may not be covered by insurance. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- injury to our reputation;
- initiation of investigations by regulators;
- significant costs to defend the claims and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize a product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- decreased demand for a product candidate, if approved for commercial sale; and
- loss of revenue.

Failure to obtain or retain 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, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also 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.

Risks Related to Manufacturing and our Dependence on Third Parties

We will rely on third parties for the manufacture of materials for our research programs, preclinical studies and clinical trials and we do not have long-term contracts with many of these parties. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We expect to rely on third parties for the manufacture of materials for our clinical trials and preclinical and clinical development. We expect to rely on third parties for commercial manufacture if any of our product candidates receive marketing approval, including Roche with respect to AT-527 for COVID-19. We do not have a long-term agreement with any of the third-party manufacturers we currently use to provide preclinical and clinical trial

materials, and we purchase any required materials on a purchase order basis. Certain of these manufacturers are critical to our production and the loss of these manufacturers to one of our competitors or otherwise, or an inability to obtain quantities at an acceptable cost or quality, could delay, prevent or impair our ability to timely conduct preclinical studies or clinical trials, and would materially and adversely affect our development and commercialization efforts.

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

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

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

Our third-party manufacturers may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity, which may impair the clinical advancement and commercialization of our product candidates.

In order to conduct clinical trials of our product candidates and commercialize any approved product, our manufacturing partners need to manufacture them in large quantities. However, they may be unable to successfully increase the manufacturing capacity for any of our product candidates or products in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities, as discussed above. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates

in sufficient quality and quantity, the development, testing and clinical trials of these product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting products may be delayed or not obtained, which could significantly harm our business. Supply sources could be interrupted from time to time and, if interrupted, it is not certain that supplies could be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost, or at all. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

We do not have multiple sources of supply for some of the components used in our product candidates, nor long-term supply contracts, and certain of our suppliers are critical to our production. If we were to lose a critical supplier, it could have a material adverse effect on our ability to complete the development of our product candidates. If we obtain regulatory approval for any of our product candidates, we would need to expand the supply of their components in order to commercialize them.

We do not have multiple sources of supply for each of the components used in the manufacturing of AT-527, AT-752, AT-787 or any of our other product candidates. For commercial supply of AT-527 for the treatment of COVID-19, we are exclusively dependent on Roche. For our other products, we have a sole supplier located in China for our active pharmaceutical ingredients. For fill-finish work, we have a supplier located in Canada and a back-up supplier located in the United States. We do not have long-term supply agreements with any of our component suppliers. We may not be able to establish additional sources of supply for our product candidates, or may be unable to do so on acceptable terms. Manufacturing suppliers are subject to cGMP quality and regulatory requirements and similar regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates and subject to ongoing inspections by applicable regulatory authorities. Manufacturing suppliers are also subject to local, state and federal regulations and licensing requirements. Failure by any of our suppliers to comply with all applicable regulations and requirements may result in long delays and interruptions in supply.

The number of suppliers of the components of our product candidates is limited. In the event it is necessary or desirable to acquire supplies from alternative suppliers, we might not be able to obtain them on commercially reasonable terms, if at all. It could also require significant time and expense to redesign our manufacturing processes to work with another company and redesign of processes can trigger the need for conducting additional studies such as comparability or bridging studies. Additionally, certain of our suppliers are critical to our production, and the loss of these suppliers to one of our competitors or otherwise would materially and adversely affect our development and commercialization efforts.

As part of any marketing approval, regulatory authorities conduct inspections that must be successful prior to the approval of the product. Failure of manufacturing suppliers to successfully complete these regulatory inspections will result in delays. If supply from the approved supplier is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through a NDA amendment or supplement, which could result in further delay. The FDA or other regulatory authorities outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

If we are unable to obtain the supplies we need at a reasonable price or on a timely basis, it could have a material adverse effect on our ability to complete the development of our product candidates or, if we obtain regulatory approval for our product candidates, to commercialize them.

We rely on third parties to conduct our preclinical studies and clinical trials. Any failure by a third party to conduct the clinical trials according to GCPs and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.

We are dependent on third parties to conduct critical aspects of our preclinical studies and clinical trials, including our ongoing Phase 1, Phase 2 and Phase 3 clinical trials for AT-527 for the treatment of COVID-19, our Phase 1 clinical trial of AT-752 for the treatment of dengue and our Phase 1/2a clinical trial of AT-787 for the treatment of HCV, and we expect to rely on third parties to conduct future clinical trials and preclinical studies for our product candidates including Roche with respect to the clinical development of AT-527. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal,

regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or research activities complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Any third parties conducting our clinical trials or preclinical studies are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash and cash equivalents or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA we submit to the FDA. Any such delay or rejection could prevent us from commercializing our product candidates.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs and substantially all our clinical trial sites have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We may collaborate with third parties for the development and commercialization of our candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our product candidates successfully, if at all.

In October 2020 we entered into the Roche License Agreement under which we granted to Roche an exclusive license related to AT-527 for certain development rights and commercialization rights outside of the United States. Additionally, we agreed that Roche would be the exclusive global supplier of AT-527 commercial product, if approved. As part of the Roche License Agreement we agreed with Roche that we would not commercialize AT-752 outside the United States unless we entered into a separate agreement with Roche to do so. We may seek additional collaborative relationships for the development and commercialization of our product candidates. If we enter into any additional such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate product revenue from these arrangements with commercial entities will depend on our collaborators' abilities to

successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into. Collaborations involving our product candidates pose the following risks to us:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information inappropriately or in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- collaborators may own or co-own intellectual property rights covering our product candidates that result from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to collaborations;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may decide not to pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors, such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction which is not in our best interest;
- collaborators may become party to a business combination transaction and the continued pursuit and emphasis on our development or commercialization program by the resulting entity under our existing collaboration could be delayed, diminished or terminated;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, devices, materials, know-how or intellectual property of the collaborator relating to our product candidates;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short- and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and

- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We may face significant competition in seeking appropriate collaborations. Business combinations among biotechnology and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate or delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Any collaborator may also be subject to many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section, and any negative impact on our collaborators may adversely affect us.

If we seek, but are not able to establish, collaborations, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital. In addition to our collaboration with Roche, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of our other product candidates.

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

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

We may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future product revenues.

In the ordinary course of our business, we may enter into collaborations, licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop new products and to pursue new markets. Proposing, negotiating and implementing collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant product revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any current or future collaborators devote to our or their future products. Disputes between us and our collaborators may result in litigation or arbitration, which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute, maintain, defend and enforce the intellectual property rights licensed to us, in which case we would depend on the ability and will of our licensors to do so. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. If our licensors do not adequately protect or enforce such licensed intellectual property, competitors may be able to use such intellectual property and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates and delay or render impossible our achievement of profitability. Further, entering into such license agreements could impose various diligence, commercialization, payment or other obligations on us, and future licensors may allege that we have breached our license agreement with them and accordingly seek to terminate our license. Any of the foregoing could adversely affect our competitive business position and have a material adverse effect on our business, financial condition, results of operations, and prospects.

Data provided by collaborators and others upon which we rely that have not been independently verified could turn out to be false, misleading or incomplete.

We rely on third-party vendors, such as CROs, scientists and collaborators to provide us with significant data and other information related to our programs, preclinical studies or clinical trials and our business. If such third parties provide inaccurate, misleading or incomplete data, our business, prospects and results of operations could be materially adversely affected.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization, could include

intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) data privacy, security, fraud and abuse and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of preclinical studies or clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

If our CMOs and CROs use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials by our CMOs and biological materials by our CROs. Our CMOs and CROs are subject to federal, state and local laws and regulations in the United States and in the countries in which they operate governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' and CRO's procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Generally, we do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Intellectual Property

If we are unable to obtain, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and product candidates, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property and prevent others from duplicating AT-511 (the free base of AT-527), AT-527, AT-281 (the free base of AT-752), AT-752, AT-777, and AT-787, or their use or manufacture, or any of our other pipeline product candidates and any future product candidates, and 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 such product candidates.

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. Although we enter into confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, CROs, consultants, scientific advisors and other contractors, any of these 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, 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, and some remain so until issued. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file any patent application related to an invention or product candidate. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The strength of patents in the pharmaceutical field involves complex legal, factual and scientific questions and can be uncertain. It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge the inventorship, ownership, validity, enforceability or scope of such patents, which may result in such patents being narrowed or invalidated, or being held unenforceable. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Additionally, any U.S. provisional patent application that we file is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of filing the related provisional patent application. If we do not timely file any non-provisional patent application, we may lose our priority date with respect to the provisional patent application and any patent protection on the inventions disclosed in the provisional patent application.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. In addition, no assurances can be given that third parties will not create similar or alternative products or methods that achieve similar results without infringing upon our patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patent applications we hold with respect to our programs or product candidates fail to issue, if the breadth or strength of protection of our current or future issued patents is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, or threaten our ability to commercialize our current or future product candidates. Several patent applications covering our product candidates have been filed recently by us. We cannot offer any assurances about which, if any, will result in issued patents, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and our patents may be challenged in courts or patent offices in the United States and abroad. In addition, the issuance of a patent does not give us the right to practice the patented invention, as third parties may have blocking patents that could prevent us from marketing our product candidate, if approved, or practicing our own patented technology.

Wide-ranging patent reform legislation in the United States, including the Leahy-Smith America Invents Act of 2011, (the "Leahy-Smith Act"), may increase the uncertainty of the strength or enforceability of our intellectual property and the cost to defend it. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and also affect patent litigation. Under the Leahy-Smith Act, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This will require us to be prompt going forward during the time from invention to filing of a patent application and to be diligent in filing patent applications, but circumstances could prevent us from promptly filing or prosecuting patent applications on our inventions. The Leahy-Smith Act also enlarged the scope of disclosures that qualify as prior art. Furthermore, if a third party filed a patent application before effectiveness of applicable provisions of the Leahy-Smith Act, on March 16, 2013, an interference proceeding in the United States can be initiated by a third party to determine if it was the first to invent any of the subject matter covered by the claims of our patent applications. We may also be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, (the "USPTO").

The Leahy-Smith Act created for the first time new procedures to challenge issued patents in the United States, including post-grant review, inter partes review and derivation proceedings, which are adversarial proceedings conducted at the USPTO, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, which all of our patent filings have, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent was filed prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of challenge, whereas inter partes review proceedings can only be brought to raise a challenge based on published prior art. These adversarial actions at the USPTO include review of patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts. The USPTO issued a final rule effective November 13, 2018 announcing that it will now use the same claim construction standard currently used in the U.S. federal courts to interpret patent claims in USPTO proceedings, which is the plain and ordinary meaning of words used. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we will be successful in defending the patent, which would result in a loss of the challenged patent right to us, including 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 technology and product candidates. 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.

As a result of all of the foregoing, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violation may result in substantial costs or prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding actual and allegations of infringement, misappropriation or other violation of the patents and other proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions, re-examination, and post-grant and inter partes review proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as oppositions before the European Patent Office, (the "EPO"). Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. Many companies in intellectual property-dependent industries, including the pharmaceutical industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. As the pharmaceutical industry expands and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to composition of matter, drug delivery, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. We cannot guarantee that our technologies, products, compositions and their uses do not or will not infringe, misappropriate or otherwise violate third-party patent or other intellectual property rights. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. In order to successfully challenge the validity of a U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any third-party patents were held by a court of competent jurisdiction to cover the composition of matter of any of our

product candidates, the manufacturing process of any of our product candidates or the method of use for any of our product candidates, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, which may not be available at all or on commercially reasonable terms, or until such patents expire.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of the merit of such claims. We may not be aware of all intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe, misappropriate or otherwise violate such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates and/or harm our reputation and financial results. Defense of these claims, regardless of their merit, could involve substantial litigation expense and could be a substantial diversion of management and employee resources from our business. 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. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, in the case of claims concerning registered trademarks, rename our product candidates, or obtain one or more licenses from third parties, which may require substantial time and monetary expenditure, and which might be impossible or technically infeasible. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

A number of companies and universities file and obtain patents in the same area as our products, which are nucleotide prodrugs, and these patent filings could be asserted against us, which may affect our business, and if successful, could lead to expensive litigation, affect the profitability of our products and/or prohibit the sale of a product or its use.

Our product candidates are nucleotide prodrugs, or nucleotide phosphoramidates. A number of companies and universities have patent applications and issued patents in this general area, including for viral indications, such as, for example, Gilead Pharmasset, LLC.; Gilead Sciences, Inc.; Merck & Co.; Bristol Myers Squibb; F. Hoffmann-La Roche; University of Cardiff; University College Cardiff Consultants; NuCana, plc; Alios Biopharma; Medivir; and others. If any of these companies or universities, or others, assert that a patent it holds is infringed by any of our product candidates or their use or manufacture, we may be drawn into expensive litigation, which may affect our business, take the time of and distract the attention of our employees, and if the litigation is successful, could affect the profitability of our products or prohibit their sale. On June 3, 2019, we received an anonymous Third Party Observation filed in connection with our international Patent Cooperation Treaty patent application for our second patent family, which covers the hemisulfate salt form of AT-511, or AT-527. The Observation generally challenges the patentability of the hemisulfate salt AT-527 over the free base AT-511. On August 1, 2019, we filed a response to the Observation describing that the AT-527 hemisulfate salt of AT-511 is not obvious in view of the AT-511 free base because AT-527 disproportionately concentrates in the liver over the heart, as shown in vivo in a dog model, which can provide an increased therapeutic effect to treat HCV, and decreased toxicity because hepatitis C is a disease of the liver. Further, while not raised in the response to the Observation, we have now also shown that AT-527 has a longer half-life and higher concentration in the lung than in the liver in vivo in monkeys, which is relevant to our COVID19 indication. On August 10, 2020, an anonymous party filed a Third Party Observation against our Patent Cooperation Treaty patent application covering a method to treat HCV patients with compensated or decompensated cirrhosis using our drug AT-527. The anonymous party asserted that it would have been obvious that the hemisulfate salt of AT-511 (AT-527) would be effective to

treat HCV-infected cirrhotic patients. We disagree for several reasons, including that the hemisulfate salt of AT-511 had not been publicly disclosed at the time of the filing of our method of treatment of cirrhosis application and second it is well known that treating HCV-infected cirrhotic patients is very difficult. Our Patent Cooperation Treaty patent application provides human data that supports the efficacy of using AT-527 to treat cirrhotic HCV-infected patients. The Third Party Observations are not acted on by the Patent Cooperation Treaty, which does not examine patent applications. The Observations by anonymous third parties as well as our responses are placed in the file and available to be read and considered by any country examining our respective patent applications. In December 2019, the U.S. Patent Office issued a patent to us covering the composition of matter AT-527. However, other than the foregoing issued U.S. patent, there can be no assurance that the Observations will not adversely affect our ability to obtain issued patents from national-stage filings of such Patent Cooperation Treaty patent applications in any jurisdictions. We may not be aware of patent claims that are currently or may in the future be pending that affect our business by the competitors working in this area. Patent applications are typically published between six and eighteen months from filing, and the presentation of new claims in already pending applications can sometimes not be visible to the public, including to us, for a period of time, or if publicly available, not yet seen by us. We cannot provide any assurance that a third party practicing in the general area of our technology will not present a patent claim that covers one or more of our products or their methods of use or manufacture at any time, including before or during this registration period. If that does occur, we may have to take steps to try to invalidate such patent or application, and we may either choose not to or may not be successful in such attempt. A license to the patent or application may not be available on commercially reasonable terms or at all.

Our products are subject to The Drug Price Competition and Patent Term Restoration Act of 1984, as amended (also referred to as the Hatch-Waxman Act), in the United States, that can increase the risk of litigation with generic companies trying to sell our products, and may cause us to lose patent protection.

Because our clinical candidates are pharmaceutical molecules reviewed by the Center for Drug Evaluation and Research of the FDA, after commercialization they will be subject in the United States to the patent litigation process of the Hatch-Waxman Act, as currently amended, which allows a generic company to submit an Abbreviated New Drug Application, ("ANDA"), to the FDA to obtain approval to sell our drug using bioequivalence data only. Under the Hatch-Waxman Act, we will have the opportunity to list our patents that cover our drug product or its method of use in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the FDA's Orange Book.

Currently, in the United States, the FDA may grant five years of exclusivity for new chemical entities, ("NCEs"), for which all of our products may qualify. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. A generic company can submit an ANDA to the FDA four years after approval of our product. The submission of the ANDA by a generic company is considered a technical act of patent infringement. The generic company can certify that it will wait until the natural expiration date of our listed patents to sell a generic version of our product or can certify that one or more of our listed patents are invalid, unenforceable or not infringed. If the latter, we will have 45 days to bring a patent infringement lawsuit against the generic company. This will initiate a challenge to one or more of our Orange Book-listed patents based on arguments from the generic company that our listed patents are invalid, unenforceable or not infringed. Under the Hatch-Waxman Act, if a lawsuit is brought, the FDA is prevented from issuing a final approval on the generic drug until 30 months after the end of our data exclusivity period, or a final decision of a court holding that our asserted patent claims are invalid, unenforceable or not infringed. If we do not properly list our relevant patents in the Orange Book, do not timely file a lawsuit in response to a certification from a generic company under an ANDA, or if we do not prevail in the resulting patent litigation, we can lose our proprietary protection, and our product can rapidly become generic. Further, even if we do correctly list our relevant patents in the Orange Book, bring a lawsuit in a timely manner and prevail in that lawsuit, the generic litigation may be at a very significant cost to us of attorneys' fees and employee time and distraction over a long period. Further, it is common for more than one generic company to try to sell an innovator drug at the same time, and so we may be faced with the cost and distraction of multiple lawsuits. We may also determine it is necessary to settle the lawsuit in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity or enforceability of our patent.

A number of pharmaceutical companies have been the subject of intense review by the FTC or a corresponding agency in another country based on how they have conducted or settled drug patent litigation, and certain reviews have led to an allegation of an antitrust violation, sometimes resulting in a

fine or loss of rights. We cannot be sure that we would not also be subject to such a review or that the result of the review would be favorable to us, which could result in a fine or penalty.

The FTC has brought a number of lawsuits in federal court in the past few years to challenge Hatch-Waxman Act ANDA litigation settlements between innovator companies and generic companies as anti-competitive. As an example, the FTC has taken an aggressive position that anything of value is a payment, whether money is paid or not. Under its approach, if an innovator as part of a patent settlement agrees not to launch or delay launch of an authorized generic during the 180-day period granted to the first generic company to challenge an Orange Book-listed patent covering an innovator drug, or negotiates a delay in entry without payment, the FTC may consider it an unacceptable reverse payment. The pharmaceutical industry argues that such agreements are rational business decisions to dismiss risk and are immune from antitrust attack if the terms of the settlement are within the scope of the exclusionary potential of the patent. In 2013, the U.S. Supreme Court, in a five-to-three decision in *FTC v. Actavis, Inc.*, rejected both the pharmaceutical industry's and FTC's arguments with regard to so-called reverse payments, and held that whether a "reverse payment" settlement involving the exchange of consideration for a delay in entry is subject to an anticompetitive analysis depends on five considerations: (a) the potential for genuine adverse effects on competition; (b) the justification of payment; (c) the patentee's ability to bring about anticompetitive harm; (d) whether the size of the payment is a workable surrogate for the patent's weakness; and (e) that antitrust liability for large unjustified payments does not prevent litigating parties from settling their lawsuits, for example, by allowing the generic to enter the market before the patent expires without the patentee's paying the generic. Furthermore, whether a reverse payment is justified depends upon its size, its scale in relation to the patentee's anticipated future litigation costs, its independence from other services for which it might represent payment, as was the case in *Actavis*, and the lack of any other convincing justification. The Court held that reverse payment settlements can potentially violate antitrust laws and are subject to the standard antitrust rule-of-reason analysis, with the burden of proving that an agreement is unlawful on the FTC, leaving to lower courts the structuring of such rule of reason analysis. If we are faced with drug patent litigation, including Hatch-Waxman Act litigation with a generic company, we could be faced with such an FTC challenge based on that activity, including how or whether we settle the case, and even if we strongly disagree with the FTC's position, we could face a significant expense or penalty.

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

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For patents that are eligible for extension of patent term, we expect to seek extensions of patent terms in the United States and, if available, in other countries, however there can be no assurance that we will be granted any patent term extension we seek, or that any such patent term extension will provide us with any competitive advantage.

The Hatch-Waxman Act in the United States provides for the opportunity to seek a patent term extension on one selected patent for each of our products, and the length of that patent term extension, if at all, is subject to review and approval by the USPTO and the FDA.

In the United States, the Hatch-Waxman Act permits one patent term extension of up to five years beyond the normal expiration of one patent per product, which if a method of treatment patent, is limited to the approved indication (or any additional indications approved during the period of extension). The length of the patent term extension is typically calculated as one half of the clinical trial period plus the entire period of time during the review of the NDA by the FDA, minus any time of delay by us during these periods. There is also a limit on the patent term extension to a term that is no greater than fourteen years from drug approval. Therefore, if we select and are granted a patent term extension on a recently filed and issued patent, we may not receive the full benefit of a possible patent term extension, if at all. We might also not be granted a patent term extension at all, because of, for example, failure to apply within the applicable period, failure to apply prior to the expiration of relevant patents or otherwise failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate product revenue.

In 1997, as part of the Food & Drug Administration Modernization Act, (the "FDAMA"), Congress enacted a law that provides incentives to drug manufacturers who conduct studies of drugs in children. The law, which provides six months of exclusivity in return for conducting pediatric studies, is referred to as the pediatric exclusivity provision. If clinical studies are carried out by us that comply with the FDAMA, we may receive an additional six-month term added to our regulatory data exclusivity period and our patent term extension period, if received, on our product. However, if we choose not to carry out pediatric studies that comply with the FDAMA, or are not accepted by the FDA for this purpose, we would not receive this additional six-month exclusivity extension to our data exclusivity or our patent term extension.

In Europe, supplementary protection certificates are available to extend a patent term up to five years to compensate for patent term lost during regulatory review, and can be extended for an additional six months if data from clinical trials is obtained in accordance with an agreed-upon pediatric investigation plan. Although all countries in Europe must provide supplementary protection certificates, there is no unified legislation among European countries and so supplementary protection certificates must be applied for and granted on a country-by-country basis. This can lead to a substantial cost to apply for and receive these certificates, which may vary among countries or not be provided at all.

If we are unable to obtain licenses from third parties on commercially reasonable terms or at all, 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 other 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 or otherwise controlling such intellectual property rights could seek either an injunction prohibiting our sales or 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 and other third parties access to the same technologies licensed to us. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, 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 technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under any future 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, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, 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, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

Although we are not currently involved in any relevant litigation, we may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our future licensors' patents, trademarks, copyrights or other intellectual property. As a result, we may need to file infringement, misappropriation or other intellectual property-related claims against third parties. To counter infringement or other unauthorized use, we may be required to file claims on a country-by-country basis, which can be expensive

and time-consuming and divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such claims, which often last for years before they are concluded.

Any claims we assert against third parties could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we have asserted are invalid or unenforceable, or both. 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 institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable.

In any such proceeding, a court may decide that a patent of ours, or a patent that we in-license, is not valid, is unenforceable and/or is not infringed, or may construe such patent's claims narrowly or 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 or defense proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or held unenforceable in whole or in part, could put our patent applications at risk of not issuing, and could limit our ability to assert those patents against those parties or other competitors and curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks, which could materially harm our business and negatively affect our position in the marketplace.

Even if we establish infringement, misappropriation or other violation of our intellectual property, the court may decide not to grant an injunction against further such activity and instead award only monetary damages, which may or may not be an adequate remedy. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

The USPTO, EPO and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay such fees due to non-U.S. patent agencies. While, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors or other third parties 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 prospects.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. Therefore, we may choose not to pursue or maintain protection for certain intellectual property in certain jurisdictions. The requirements for patentability may differ in certain countries, particularly in developing countries. 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 may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, may not favor the enforcement of our patents and other intellectual property rights.

This could make it difficult for us to stop the infringement of our patents or the misappropriation or other violation of our other intellectual property rights. A number of foreign countries have stated that they are willing to issue compulsory licenses to patents held by innovator companies on approved drugs to allow the government or one or more third-party companies to sell the approved drug without the permission of the innovator patentee where the foreign government concludes it is in the public interest. India, for example, has used such a procedure to allow domestic companies to make and sell patented drugs without innovator approval. There is no guarantee that patents covering any of our drugs will not be subject to a compulsory license in a foreign country, or that we will have any influence over if or how such a compulsory license is granted. Further, Brazil allows its regulatory agency ANVISA to participate in deciding whether to grant a drug patent in Brazil, and patent grant decisions are made based on several factors, including whether the patent meets the requirements for a patent and whether such a patent is deemed in the country's interest. In addition, several other countries have created laws that make it more difficult to enforce drug patents than patents on other kinds of technologies. Further, under the treaty on the Trade-Related Aspects of Intellectual Property (the "TRIPS"), as interpreted by the Doha Declaration, countries in which drugs are manufactured are required to allow exportation of the drug to a developing country that lacks adequate manufacturing capability. Therefore, our drug markets in the United States or foreign countries may be affected by the influence of current public policy on patent issuance, enforcement or involuntary licensing in the healthcare area.

In addition, in November 2015, members of the World Trade Organization (the "WTO"), which administers TRIPS, voted to extend the exemption against enforcing pharmaceutical drug patents in least developed countries until 2033. We currently have no patent applications filed in least developed countries, and our current intent is not to file in these countries in the future, at least in part due to this WTO pharmaceutical patent exemption.

Furthermore, the WTO is currently considering a waiver of intellectual property rights for COVID-19 vaccines and the U.S. government recently took a stance in support of the waiver. The current proposal is for a temporary waiver of intellectual property rights that cover COVID-19 vaccines, however, the ultimate timing and scope of the waiver, if approved, is unknown. The scope and timing of such waiver will likely be subject to extensive negotiations given the complexity of the matter, which may result in prolonged uncertainty and therefore could adversely affect our business. If a waiver is approved and covers COVID-19 treatments, such as AT-527, our ability to successfully commercialize AT-527 and protect our related technology could be adversely affected.

We rely on our ability to stop others from competing by enforcing our patents, however some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties, in certain circumstances. For example, compulsory licensing, or the threat of compulsory licensing, of life-saving products and expensive products is becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Compulsory licenses could be extended to include some of our product candidates, if they receive marketing approval, which may limit our potential revenue opportunities. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may also 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, if our ability to enforce our patents to stop infringing activities is inadequate. 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. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products where such patent rights exist, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement if a government is the infringer, which could materially diminish the value of the patent.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is either not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, CROs, consultants, scientific advisors and other contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and our trade secrets could be disclosed, and we may not have adequate remedies for any such breach. 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. Misappropriation or unauthorized disclosure of our trade secrets or other confidential proprietary information could cause us to lose trade secret protection, impair our competitive position and have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets or other confidential proprietary information are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret or other confidential proprietary information.

Further, we cannot provide any assurances that competitors or other third parties will not otherwise gain access to our trade secrets and other confidential proprietary information or independently discover or develop substantially equivalent technology and processes. If we are unable to prevent disclosure of the trade secrets and other non-patented intellectual property related to our product candidates and technologies to third parties, there is no guarantee that we will have any such enforceable trade secret protection and we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, that our employees have wrongfully used or

disclosed alleged trade secrets of their former employers, or asserting ownership of what we regard as our own intellectual property.

We have employed, and may in the future employ, individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of such individuals' former employers or other third parties. 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, or our ability to hire personnel, which, in any case of the foregoing, could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Although it is our policy to require all of our employees and consultants to assign their inventions to us, to the extent that employees or consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. We may also 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 prospects.

Our proprietary rights may not adequately protect our technologies and product candidates, and intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of our patents;
- others, including inventors or developers of our patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- we might not have been the first to conceive and reduce to practice the inventions covered by our patents or patent applications;
- we might not have been the first to file patent applications covering certain of our inventions;
- 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;
- our pending patent applications might not result in issued patents;
- there might be prior public disclosures that could invalidate our patents;
- our issued patents may not provide us with any commercially viable products or competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- the Supreme Court of the United States, other U.S. federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our patents;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- ownership, validity or enforceability of our patents or patent applications may be challenged by third parties; and
- the patents or pending or future applications of third parties, if issued, may have an adverse effect on our business.

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

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We expect to experience significant growth over time in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, regulatory and clinical affairs and sales, marketing and distribution. To manage our growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. As we expand our organization, we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including:

- the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow product revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of clinical trial conduct and execution, and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by 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, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Many of the biotechnology and pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited.

We only have a limited number of employees to manage and operate our business.

As of May 13, 2021, we had 42 full-time employees. Our focus on the development of AT-527 alone requires us to manage and operate our business in a highly efficient manner. We cannot assure you that we will be able to hire and/or retain adequate staffing levels to develop our product candidates or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers or other significant personnel or experience increases in our compensation costs, our business may materially suffer.

We are highly dependent on our management and directors, including our Chief Executive Officer, Jean-Pierre Sommadossi, Ph.D., among others. Due to the specialized knowledge each of our officers and key employees possesses with respect to our product candidates and our operations, the loss of service of any of our officers or directors could delay or prevent the successful enrollment and completion of our clinical trials. We do not carry key person life insurance on any officers or directors. In general, the employment arrangements that we have with our executive officers do not prevent them from terminating their employment with us at any time.

In addition, our future success and growth will depend in part on the continued service of our directors, employees and management personnel and our ability to identify, hire and retain additional personnel. If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult or costly and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or effectively incentivize these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

Many of our employees have become or will soon become vested in a substantial amount of our common stock or options to purchase our common stock. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements entered into in connection with the IPO. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. For example, the COVID-19 pandemic has resulted in widespread unemployment, an economic slowdown and extreme volatility in the capital markets. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, there is a risk that one or more of our CROs, suppliers, CMOs or other third-party providers may not survive an economic downturn. As a result, our business, results of operations and price of our common stock may be adversely affected.

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets, and our business, which could reduce our share price.

Following a national referendum and enactment of legislation by the government of the U.K., the U.K. formally withdrew from the EU on January 31, 2020, commonly referred to as "Brexit" and, following the expiration of the Brexit transitional period on December 31, 2020, the U.K. now operates under a distinct regulatory regime and certain EU laws now only apply to the U.K. in respect of Northern Ireland (as laid out in the Protocol on Ireland and Northern Ireland, including but not limited to marketing authorizations). The Medicines and Healthcare products Regulatory Agency is now the U.K.'s standalone regulator. Although the U.K. and European Union have now reached an agreement on its future trading relationship (implemented in the EU-U.K. Trade and Cooperation Agreement from January 1, 2021 ("TCA")), the agreement does not cover all regulatory areas regarding supply of

medicinal product, which will likely be subject to future bilateral discussions going forward and could further change the relationship between the U.K. and the EU in this regard.

While agreement on the terms of the TCA has avoided a “no deal” Brexit scenario, and provides in principle for quota and tariff free trading of goods, it is nevertheless expected that the TCA will result in the creation of non-tariff barriers (such as increased shipping and regulatory costs and complexities) to the trade in goods between the UK and EU. Further, the TCA does not provide for the continued free movement of services between the UK and EU and also grants each of the U.K. and EU the ability, in certain circumstances, to unilaterally impose tariffs on one another. The TCA does provide for the mutual recognition of cGMP inspections of manufacturing facilities for medicinal products and cGMP documents issued. However, it is important to note that significant regulatory gaps still exist and the TCA does not contain wholesale mutual recognition of U.K. and EU pharmaceutical regulations and product standards between the parties, for example, in relation to batch testing and pharmacovigilance, which remain subject to further discussions.

These developments have had and may continue to have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in the United Kingdom and in Europe. As a result of this uncertainty, global financial markets could experience significant volatility, which could adversely affect the market price of our common stock. Asset valuations, currency exchange rates, and credit ratings may also be subject to increased market volatility. Lack of clarity about future U.K. laws and regulations as the United Kingdom determines which European Union rules and regulations to replace or replicate after withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, data protection laws, supply chain logistics, environmental, health, and safety laws and regulations, immigration laws, and employment laws, could decrease foreign direct investment in the United Kingdom, increase costs, depress economic activity, and restrict our access to capital. If the United Kingdom and the European Union are unable to negotiate acceptable withdrawal terms or if other EU Member States pursue withdrawal, barrier-free access between the United Kingdom and other EU Member States or among the European Economic Area overall could be diminished or eliminated.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. Depending on the terms of Brexit, the United Kingdom could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers that could make our doing business in Europe more difficult. In addition, currency exchange rates between the pound sterling, the euro and the U.S. dollar have already been, and may continue to be, affected by Brexit.

Risks Related to Our Common Stock

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

Our executive officers, directors, and 5% stockholders beneficially own at least 30% of our common stock as of May 13, 2021. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine matters requiring stockholders 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 shares of common stock that you may feel are in your best interest as one of our stockholders.

A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have 82,736,937 outstanding shares of common stock as of May 13, 2021. Substantially all of these shares are eligible for sale. Additionally, holders of an aggregate of 57,932,090 shares of our common stock have rights, subject to specified 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, until such shares can otherwise be sold without restriction under Rule 144 of the Securities Act of 1933, as amended, or until the rights terminate pursuant to the terms of the stockholders' agreement between us and such holders. We also have registered all shares of common stock that we may issue under our equity compensation plans and these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

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

We are an “emerging growth company,” as defined in the JOBS Act, and may remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of the closing of our IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common shares that are held by non-affiliates to exceed \$700 million as of the last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- 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.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

Based on our current market capitalization we may become a large accelerated filer for the year ended December 31, 2021 in which case we would lose our status as an emerging growth company. The final determination will not be known until June 30, 2021, the last day of our second fiscal quarter in 2021.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline, even if our business is doing well.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We currently have limited research coverage by securities and industry analysts. If any of the analysts who cover us or may cover us downgrades our common stock or issues an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our target preclinical studies or clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions may also limit the price that investors are willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our restated certificate of incorporation, specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders, other than suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction and any action that the Court of Chancery of the State of Delaware has dismissed for lack of subject matter jurisdiction, which may be brought in another state or federal court sitting in the State of Delaware. Our restated certificate of incorporation also specifies that unless we consent in writing to the selection of an alternate forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation described above.

We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes or federal judges experienced in resolving Securities Act disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

General Risk Factors

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

Until such time, if ever, as we can generate substantial revenue from product sales, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our operations, our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, redeeming our stock, making certain investments and engaging in certain merger, consolidation or asset sale transactions, among other restrictions. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Weakening patent laws and enforcement by courts and other authorities in the United States and other jurisdictions may impact our ability to protect our patents.

The U.S. Supreme Court has issued opinions in patent cases in the last few years that many consider may weaken patent protection in the United States, either by narrowing the scope of patent protection available in certain circumstances, holding that certain kinds of innovations are not patentable or generally otherwise making it easier to invalidate patents in court. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making and other bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce and defend our existing patents and patents that we might obtain in the future.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed. For example, we could become a party to foreign opposition proceedings, such as at the EPO, or patent litigation and other proceedings in a foreign court. If so, uncertainties resulting from the initiation and continuation of such proceedings could have a material adverse effect on our ability to compete in the marketplace. The cost of foreign adversarial proceedings can also be substantial, and in many foreign jurisdictions, the losing party must pay the attorney fees of the winning party.

We may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause or to incur debt or assume contingent liabilities, and subject us to other risks.

In the future, we may enter into transactions to acquire other businesses, products or technologies or enter into strategic partnerships, including licensing. If we do identify suitable acquisition or partnership candidates, we may not be able to make such acquisitions or partnerships on favorable terms, or at all. Any acquisitions or partnerships we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors, and we may never realize the anticipated benefits of such acquisitions or partnerships. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business or partnership that are not covered by the indemnification we may obtain from the seller or our partner. In addition, we may not be able to successfully integrate any acquired personnel, technologies and operations into our

existing business in an effective, timely and non-disruptive manner. Acquisitions or partnerships may also divert management attention from day-to-day responsibilities, lead to a loss of key personnel, increase our expenses and reduce our cash and cash equivalents available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or partnerships or the effect that any such transactions might have on our operating results.

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

Natural disasters or pandemics, other than or in addition to COVID-19, could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, pandemic, such as the COVID-19 pandemic, or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Litigation against us could be costly and time-consuming to defend and could result in additional liabilities.

We may from time to time be subject to legal proceedings and claims that arise in the ordinary course of business or otherwise, such as claims brought by our customers or third parties in connection with commercial disputes and employment claims made by our current or former employees. Claims may also be asserted by or on behalf of a variety of other parties, including government agencies, patients or vendors of our customers, or stockholders.

Any litigation involving us may result in substantial costs, operationally restrict our business, and may divert management's attention and resources, which may seriously harm our business, overall financial condition and results of operations. Insurance may not cover existing or future claims, be sufficient to fully compensate us for one or more of such claims, or continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, thereby adversely impacting our results of operations and resulting in a reduction in the trading price of our stock.

The market price of our common stock has been volatile and may fluctuate substantially.

Our stock price has been and is likely to remain volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at a profit. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- actual or expected changes in our growth rate relative to our competitors;
- results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development of our product candidates or those of our competitors;
- unanticipated serious safety concerns related to the use of our product candidates;
- developments related to our existing or any future collaborations;
- developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- regulatory or legal developments in the United States and other countries;
- development of third-party product candidates that may address our markets and make our product candidates less attractive;

- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our failure to commercialize our product candidates;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- changes in accounting practices;
- the trading volume of our common stock;
- our cash and cash equivalents position;
- our ability to effectively manage our growth;
- sales of our common stock by us or our stockholders in the future;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- ineffectiveness of our internal controls;
- significant lawsuits, including intellectual property or stockholder litigation;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In addition, the stock market in general, and The Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common shares, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources, which would harm our business, financial condition and results of operations.

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur before we became a public company in October 2020. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection

Act, the listing requirements of the Nasdaq Global Select 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. Our management and other personnel are devoting a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are 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 Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), in our second annual report due to be filed with the SEC after becoming a public company, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we need to continue to dedicate internal resources, engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. 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 Section 404. We may discover significant deficiencies or material weaknesses in our internal control over financial reporting, which we may not successfully remediate on a timely basis or at all. Any failure to remediate any significant deficiencies or material weaknesses identified by us or to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. 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.

If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.

We are not currently required to comply with the rules of the SEC implementing Section 404 and, therefore, we are not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. We are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. Although we will be required to disclose changes made in our internal controls and procedures on a quarterly basis, we are not required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until the year following our first annual report required to be filed with the SEC. As an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event material weaknesses have been identified in our internal control over financial reporting.

To comply with the requirements of being a public company, we have undertaken and will need to undertake additional actions, such as implementing new internal controls and procedures and hiring additional accounting or internal audit staff. Testing and maintaining internal control can divert our management's attention from other matters that are important to the operation of our business. In addition, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal controls over financial reporting or we are unable to comply with the

requirements of Section 404 in a timely manner or 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 once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports. As a result, the market price of our common stock could be materially adversely affected.

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

We are subject to the periodic reporting requirements of the Exchange Act. We are continuing to refine our disclosure controls and procedures to provide reasonable assurance 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, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, is likely to be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain all available funds and future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock is likely to be your sole source of gain on an investment in our common stock for the foreseeable future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

Recent Sales of Unregistered Securities; Purchases of Equity Securities by the Issuer or Affiliated Purchaser

None.

Use of Proceeds

On November 3, 2020, we completed the initial public offering ("IPO") of our common stock pursuant to which we issued and sold 14,375,000 shares of our common stock at a price to the public of \$24.00 per share.

All shares issued and sold in the initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No.333-249404), as amended (the "Registration Statement"), declared effective by the SEC on October 29, 2020.

We received net proceeds of approximately \$317.6 million after deducting underwriting discounts and commissions and offering expenses.

The remaining net proceeds from our IPO have been invested primarily in money market accounts. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our Prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 29, 2020.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed/ Furnished Herewith
		Form	File No.	Exhibit		
3.1	Restated Certificate of Incorporation.	8-K	001-39661	3.1	11/5/2020	
3.2	Amended and Restated Bylaws.	8-K	001-39661	3.2	11/5/2020	
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1	333-249404	4.2	10/9/2020	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.					**
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.					**
101.INS	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*

* Filed herewith.

** Furnished herewith.

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.

ATEA PHARMACEUTICALS, INC.

Date: May 13, 2021

By: /s/ Jean-Pierre Sommadossi, Ph.D.
Jean-Pierre Sommadossi, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Date: May 13, 2021

By: /s/ Andrea Corcoran
Andrea Corcoran
Chief Financial Officer, Executive Vice President, Legal and
Secretary
(principal financial officer)

CERTIFICATION

I, Jean-Pierre Sommadossi, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Atea Pharmaceuticals, 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)) 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) [Omitted];
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; 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: _____
Jean-Pierre Sommadossi, Ph.D.
President and Chief Executive Officer
(principal executive officer)

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

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

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 13, 2021

By: _____
Jean-Pierre Sommadossi, Ph.D.
President and Chief Executive Officer
(principal executive officer)

