

PROSPECTUS

12,500,000 Shares**Common Stock**

This is Atea Pharmaceuticals, Inc.'s initial public offering. We are offering 12,500,000 shares of our common stock. Prior to this offering, there has been no public market for our common stock.

The initial public offering price of our common stock is \$24.00 per share. The shares will trade on The Nasdaq Global Select Market under the symbol "AVIR."

We are an "emerging growth company" under the federal securities laws and, as such, are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in our common stock involves risks that are described in the "[Risk Factors](#)" section beginning on page 12 of this prospectus.

	Per Share	Total
Initial public offering price	\$ 24.00	\$ 300,000,000
Underwriting discounts and commissions paid by us(1)	\$ 1.68	\$ 21,000,000
Proceeds, before expenses, to us	\$ 22.32	\$ 279,000,000

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. We refer you to "Underwriting" beginning on page 190 for additional information regarding underwriting compensation.

We have granted the underwriters an option for a period of 30 days to purchase up to 1,875,000 additional common shares at the public offering price less underwriting discounts and commissions. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$24,150,000, and the total proceeds to us, before expenses, will be \$320,850,000.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about November 3, 2020 through the book-entry facilities of the Depository Trust Company.

J.P. Morgan**Morgan Stanley****Evercore ISI****William Blair**

The date of this prospectus is **October 29, 2020**.

TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY	1
RISK FACTORS	12
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	85
MARKET AND INDUSTRY DATA	87
USE OF PROCEEDS	88
DIVIDEND POLICY	90
CAPITALIZATION	91
DILUTION	93
SELECTED CONSOLIDATED FINANCIAL DATA	95
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	97
BUSINESS	109
MANAGEMENT	152
EXECUTIVE AND DIRECTOR COMPENSATION	159
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	172
PRINCIPAL STOCKHOLDERS	175
DESCRIPTION OF CAPITAL STOCK	178
SHARES ELIGIBLE FOR FUTURE SALE	183
MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS	186
UNDERWRITING	190
LEGAL MATTERS	199
EXPERTS	199
WHERE YOU CAN FIND MORE INFORMATION	199
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS	F-1

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus related thereto is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

We have proprietary rights to trademarks, trade names and service marks appearing in this prospectus that are important to our business. Solely for convenience, the trademarks, trade names and service marks may appear in this prospectus without the ® and TM symbols, but any such references are not intended to indicate, in any

[Table of Contents](#)

way, that we forgo or will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, trade names and service marks. All trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and consolidated financial statements included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this entire prospectus, including the information under the sections titled “Risk Factors,” “Special Note Regarding Forward-Looking Statements” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to “Atea Pharmaceuticals,” “Atea,” the “Company,” “we,” “us” and “our” refer to Atea Pharmaceuticals, Inc. and its consolidated subsidiary. As used in this prospectus, unless the context otherwise requires, references to “Roche” refer to F. Hoffman-La Roche Ltd and Genentech, Inc.

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, or ssRNA, viruses, which are a prevalent cause of severe viral diseases. Currently, we are focused on the development of orally available, potent, and selective nucleotide prodrugs for difficult-to-treat, life-threatening viral infections, including severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, the virus that causes COVID-19, hepatitis C virus, or HCV, dengue virus, and respiratory syncytial virus, or RSV. We believe our team’s expertise from decades of developing innovative antiviral treatments uniquely positions us to advance medicines that have the potential to cure some of the world’s most severe viral diseases by inhibiting the enzymes central to viral replication.

All of our product candidates have been discovered and developed internally and we retain full global rights to commercialize our product candidates, other than certain ex-U.S. rights licensed to Roche under the license agreement we entered into with Roche in October 2020, or the Roche License Agreement. We retain the right to commercialize all our product candidates in the United States. The following table summarizes our orally administered product candidate pipeline.

ssRNA virus	Indication	Product candidate	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
Coronaviridae	COVID-19 ¹	AT-527 ²					Prior to end of 2020 <ul style="list-style-type: none"> Initiate virology/PK substudy Report Phase 2 interim safety data First half of 2021 <ul style="list-style-type: none"> Complete enrollment and report Phase 2 topline data Initiate Phase 3 outpatient trial Second half of 2021 <ul style="list-style-type: none"> Initiate Phase 3 post-exposure prophylaxis trial
Flaviviridae	Hepatitis C (HCV)	AT-787 ² (fixed-dose combo of AT-527 & 777)					First half of 2021 <ul style="list-style-type: none"> Initiate Phase 1 trial Second half of 2021 <ul style="list-style-type: none"> Initiate Phase 2 trial
		AT-777 (NS5A inhibitor)					
Flaviviridae	Dengue ³	AT-752 ³					First half of 2021 <ul style="list-style-type: none"> Initiate and complete Phase 1 trial Initiate Phase 2 trial Second half of 2021 <ul style="list-style-type: none"> Report Phase 2 topline data
Paramyxoviridae	RSV	AT-889, AT-934 and other candidates					Second half of 2021 <ul style="list-style-type: none"> Initiate and complete Phase 1 trial Initiate Phase 2 trial

¹ In October 2020, we licensed to Roche the ex-U.S. development and commercialization rights to AT-527 (other than for certain hepatitis C virus uses). See “Business – Roche License Agreement.”

² AT-787 is our selected product candidate for the treatment of HCV

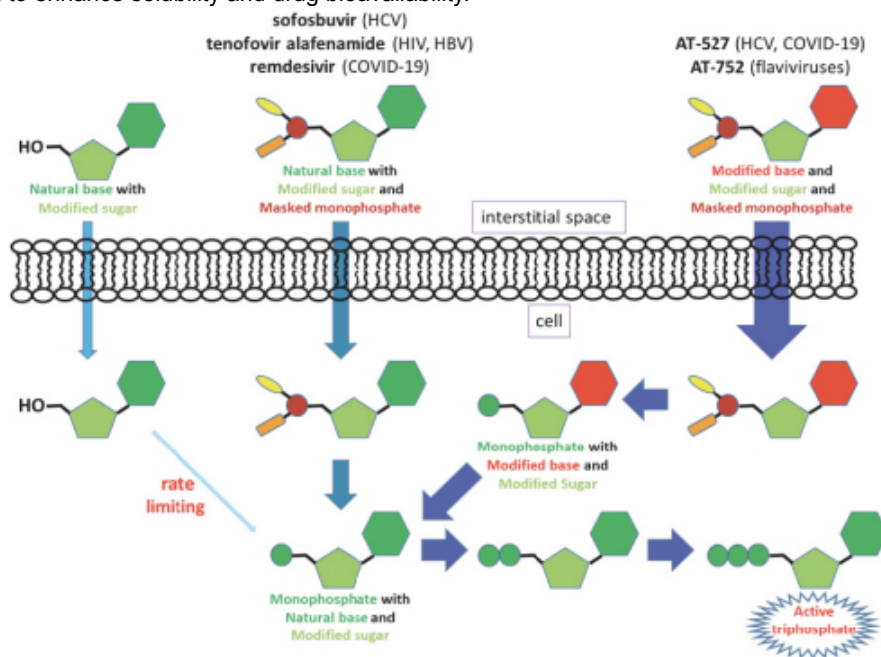
³ In October 2020, as a part of the Roche License Agreement we retained rights to develop and manufacture AT-752 globally and to commercialize AT-752 in the United States for dengue, Japanese Encephalitis, West Nile virus, Yellow Fever and Zika. We agreed with Roche that we would not commercialize AT-752 outside the United States unless we entered into a separate commercialization agreement with Roche to do so.

Our platform

Over the last 40 years, nucleoside and nucleotide, or together, nucleos(t)ide, analogs have been developed to mimic naturally occurring nucleic acids and block viral replication by inhibiting enzymes involved in RNA and DNA viral growth cycles. Nucleos(t)ide analogs have become the backbone of therapies that treat life-threatening viral infections, including human immunodeficiency virus, or HIV, hepatitis B, or HBV, and HCV. Our expertise has allowed us to develop a proprietary platform, which facilitates the development of product candidates that combine unique purine nucleotide scaffolds with a novel double prodrug strategy. We believe that utilizing this double prodrug moiety approach allows us to maximize formation of the active metabolite, potentially resulting in highly potent and selective oral antiviral product candidates.

Our proprietary nucleotide prodrug platform, as illustrated below, is comprised of the following critical components:

- Specific modifications of the purine base, acting as a prodrug, enhance cell membrane permeability, resulting in an intermediate metabolite that maximizes formation of the triphosphate active metabolite in cells;
- Stereospecific phosphoramidate, acting as a prodrug, designed to bypass the first rate-limiting phosphorylation enzyme in the intracellular activation pathway;
- Specific modifications in the sugar moiety of the purine nucleotide scaffold, producing potent antiviral activity with a high degree of selectivity; and
- Highly specific salt form to enhance solubility and drug bioavailability.



We have produced a large library of nucleotide and nucleoside prodrugs specifically designed to target viral RNA dependent RNA polymerase, or RdRp, a key enzyme that is encoded in the viral genome. All ssRNA viruses,

including SARS-CoV-2 and HCV, depend on RdRp for replication and transcription and, since viral RdRp is not present in the host cell, RdRp is an ideal target to inhibit virus replication.

Our product candidates

AT-527 for the treatment of COVID-19

Our lead product candidate, AT-527, is an orally administered, novel antiviral agent for the treatment of patients infected with SARS-CoV-2, which causes COVID-19. AT-527 was specifically designed as a purine nucleotide prodrug to inhibit RdRp. The RdRps in SARS-CoV-2 support the transcription and replication of the approximately 30,000-nucleotide RNA viral genome. The RdRps in SARS-CoV-2 and severe acute respiratory syndrome coronavirus 1, or SARS-CoV, the virus that causes severe acute respiratory syndrome, are the largest and most complex RdRps among RNA viruses. *In vitro* preclinical studies measuring the antiviral activity of AT-527 in several assays against human coronavirus, including SARS-CoV and SARS-CoV-2, suggest that AT-527 is potent and highly selective against these viruses. We are currently evaluating AT-527 in a randomized, double blind, placebo-controlled Phase 2 trial in approximately 190 adult patients with moderate COVID-19 and one or more risk factors for poor outcomes. AT-527 was well tolerated and exhibited highly potent antiviral activity in two clinical trials with HCV infected subjects. We have utilized the pharmacokinetics, safety and tolerability data we obtained from our clinical trials of AT-527 for the treatment of HCV to advance the clinical development of AT-527 for the treatment of COVID-19. HCV was the initial therapeutic indication for which we evaluated AT-527. We dosed our first patient in September 2020 and expect to report topline data from this COVID-19 trial in the first half of 2021. We anticipate initiating a Phase 3 clinical trial to study AT-527 in adult patients with mild to moderate COVID-19 requiring outpatient management in the first half of 2021. In October 2020, we entered into the Roche License Agreement, granting Roche an exclusive license over the development and commercialization rights related to AT-527 outside of the United States (other than for certain hepatitis C virus uses). We also granted Roche a license to manufacture AT-527 worldwide and agreed that Roche would manufacture the global commercial supply of AT-527. As part of the consideration, Roche agreed to pay us an upfront payment of \$350 million, or the Roche Upfront Payment. See “Business – Roche License Agreement.”

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 have created a novel combination of AT-527 with AT-777, a nonstructural protein 5A, or NS5A, inhibitor into a single, oral, pan-genotypic fixed dose combination product candidate, AT-787, for the treatment of chronic HCV infection. Despite significant recent advances in treatment, HCV remains a global health burden due to the limitations of currently available treatment options. We believe that AT-787 has the potential to offer a short duration protease-sparing regimen for HCV-infected patients with or without cirrhosis. For patients with decompensated cirrhosis, a life-threatening stage of liver disease, AT-787 has the potential to treat these patients without the co-administration of ribavirin. Upon the resolution of industry wide clinical trial challenges associated with the COVID-19 pandemic, we expect to restart our Phase 1/2A clinical trial, which is designed to evaluate the safety and pharmacokinetics, or PK, of different dosages of AT-777 in healthy adults and to evaluate the combination of AT-527 and AT-777 in HCV infected subjects.

AT-752 for the treatment of dengue

AT-752 is an oral, purine nucleotide prodrug for the treatment of dengue virus – a mosquito-borne viral infection that infects up to 400 million people a year for which there are currently no therapies approved by

either the U.S. Federal Food and Drug Administration, or the FDA, or European Medicines Agency, or EMA. AT-752 targets the inhibition of the dengue viral polymerase and, in preclinical studies, AT-752 showed potent *in vitro* activity against all serotypes tested as well as potent *in vivo* antiviral activity in a small animal model. We plan to submit an investigational new drug application, or IND, to the FDA or Clinical Trial Application to the one or more competent authorities outside the United States in the first half of 2021. Contingent upon receipt of FDA or EMA authorization, we expect to initiate a randomized, double-blind, placebo-controlled Phase 1 trial to analyze the safety and PK of several different dosages of AT-752 in healthy adult subjects in the first half of 2021. Following the completion of the Phase 1 trial, we expect to initiate a Phase 2 trial to evaluate the antiviral activity, safety and PK of AT-752 in adult patients with dengue in the first half of 2021. Pursuant to the Roche License Agreement we retained rights to develop and manufacture AT-752 globally and to commercialize AT-752 in the United States for dengue, Japanese Encephalitis, West Nile virus, Yellow Fever and Zika. Rights to AT-752 for other indications were exclusively licensed to Roche. Roche agreed to negotiate in good faith an amendment to the Roche License Agreement pursuant to which Roche may commercialize AT-752 for Dengue outside of the United States, unless Roche offers such commercialization right to us. Neither Roche nor we may commercialize AT-752 outside of the United States for Dengue until we agree to an amendment to the Roche License Agreement. See “Business – Roche License Agreement.”

AT-889, AT-934 and other product candidates for the treatment of respiratory syncytial virus

We are evaluating two lead compounds, AT-889 and AT-934, second generation nucleoside pyrimidine prodrugs and other compounds for the treatment of RSV. RSV is a seasonal respiratory virus that can be serious for infants, older adults, and the immuno-compromised population. AT-889 and AT-934 inhibit RNA polymerase through both initiation of viral replication and viral transcription and showed potent *in vitro* activity in several cell based assays against RSV. We expect to nominate a product candidate and to initiate clinical development of the selected product candidate in the second half of 2021. We believe that the product candidate we develop, if approved, could be the first therapy in over 30 years to be approved specifically for the treatment of RSV.

Our team

Our management team has significant experience discovering, developing and commercializing antiviral therapies for life threatening viral infections. Our Founder, Chairman, and Chief Executive Officer, Jean-Pierre Sommadossi, Ph.D., has over 30 years of scientific, operational, strategic, and management experience in the biopharmaceutical industry and holds more than 60 U.S. patents related to the treatment of infectious disease and cancer. Dr. Sommadossi was the principal founder of Idenix Pharmaceuticals, Inc., or Idenix, which was acquired by Merck & Co., Inc. in 2014, and a co-founder of Pharmasset, Inc., or Pharmasset, which was acquired by Gilead Sciences, Inc. in 2012.

We have assembled an experienced management and scientific team with a track record of success in the field of antiviral drug development, many of whom have worked together previously. Our team has significant expertise in nucleos(t)ide chemistry and biology and has applied that expertise towards the discovery and development of innovative antiviral treatments, including Epivir, Sovaldi, Tyzeka, Valtrex, Wellferon, Videx, Reyataz, Sustiva, Mavyret, Xofluza, Relenza and Zerit. Members of our team have held senior positions at AstraZeneca plc, GlaxoSmithKline plc, Chiron, Novartis International AG, Biogen, F. Hoffmann La Roche, Abbvie, Bristol Myers Squibb, Shire, Biohaven Pharma, Pharmasset, Idenix, Valeant Pharmaceuticals International and Alnylam Pharmaceuticals.

We have been supported by a leading syndicate of investors, which include Adage, Aju IB Investment, Ally Bridge Group, Bain Capital Life Sciences, Cormorant Asset Management, Morningside Ventures, Omega Funds,

Perceptive Advisors, PICTET, RA Capital, Redmile Group, RMI Partners, Rock Springs Capital, Sectoral Asset Management, T. Rowe Price and Valence Life Sciences.

Our strategy

Our goal is to become a global leader in the discovery, development, and commercialization of novel antiviral therapies for severe or life threatening viral infections. We intend to achieve this goal by pursuing the following strategies:

- rapidly complete development and obtain approval for our lead product candidate, AT-527, an oral drug for the treatment of COVID-19;
- deploy our medicinal chemistry expertise and proprietary purine nucleotide platform against severe ssRNA viruses with high unmet need;
- focus on excellent clinical and regulatory execution;
- maximize the value of our product candidates; and
- maintain our entrepreneurial outlook, scientifically rigorous approach, and culture of tireless commitment to patients.

Recent Developments

In October 2020, we issued and sold 8,973,261 shares of our Series D-1 convertible preferred stock to certain existing investors at a price of \$11.98 per share for an aggregate purchase price of \$107.5 million. We refer to this issuance in this prospectus as the “Series D-1 Closing.” See “Management’s Discussion and Analysis of Financial Condition and Results of Operation—Liquidity and Capital Resources—Sources of Liquidity” for more information.

Risk Factors

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include the following:

- there is significant uncertainty around our development of AT-527 as a potential treatment for COVID-19;
- COVID-19 may materially and adversely affect our business, financial results and clinical trials;
- 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 and expect to incur significant additional losses for the foreseeable future. We have no products that have generated any commercial revenue and we may never achieve or maintain profitability;
- even if we consummate this offering, 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 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 do not receive regulatory approval or are not successfully commercialized, or are significantly delayed in doing so, our business will be harmed;

- developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets;
- we will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations;
- an active trading market for our common stock may not develop; and
- the market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Implications of Being an Emerging Growth Company

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As such, we may take advantage of certain exemptions from various reporting requirements that are otherwise applicable to public companies. These exemptions include, but are not limited to:

- the option to present only two years of audited financial statements and only two years of related “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as “say-on-pay,” “say-on-frequency,” and “say-on-golden parachutes;” and
- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation.

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.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if prior to the end of such five-year period, (i) our annual gross revenue exceeds \$1.07 billion, (ii) we issue more than \$1.0 billion of non-convertible debt in any three-year period or (iii) we become a “large accelerated filer” (as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act), we will cease to be an emerging growth company prior to the end of such five-year period. We will be deemed to be a “large accelerated filer” at such time that we (a) have an aggregate worldwide market value of common equity securities held by non-affiliates of \$700.0 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act for a period of at least 12 months, (c) have filed at least one annual report pursuant to the Exchange Act, and (d) are not eligible to use the requirements for “smaller reporting companies” (as defined in Rule 12b-2 of the Exchange Act) under the revenue test for smaller reporting companies.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

Corporate Information

We were incorporated under the laws of the state of Delaware in July 2012. Our principal executive offices are located at 125 Summer Street, Boston, Massachusetts 02110 and our telephone number is (857) 284-8891. Our website address is www.ateapharma.com. The information contained in, or accessible through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

The Offering

Common stock offered by us	12,500,000 shares.
Common stock to be outstanding after this offering	80,741,937 shares (or 82,616,937 shares if the underwriters exercise their option to purchase additional shares in full).
Option to purchase additional shares	The underwriters have a 30-day option to purchase up to 1,875,000 additional shares of our common stock at the initial public offering price less underwriting discounts and commissions.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately \$275.8 million (or approximately \$317.7 million if the underwriters exercise in full their option to purchase additional shares of common stock), after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We anticipate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents, the proceeds from the Series D-1 Closing and the Roche Upfront Payment, to advance (i) the development of our AT-527 program for the treatment of COVID-19 through Phase 3 clinical trials; (ii) the development of our AT-787 program for the treatment of HCV through the completion of our planned Phase 2 clinical trial; (iii) the development of our AT-752 program for the treatment of dengue through the completion of our planned Phase 2 clinical trial; (iv) the development of AT-889, AT-934 and other product candidates for the treatment of RSV through the completion of our planned Phase 2 clinical trial; and (v) the remainder to fund the continued expansion of our platform technology, preclinical studies for research stage programs, working capital, and other general corporate purposes. See "Use of Proceeds" for additional information.
Risk factors	You should carefully read the "Risk Factors" beginning on page 12 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Nasdaq Global Select Market symbol	"AVIR"

The number of shares of our common stock to be outstanding after this offering is based on 10,309,847 shares of our common stock outstanding as of September 30, 2020, which includes 200,000 shares of unvested restricted stock subject to repurchase, and excludes:

- 4,186,747 shares of our common stock issuable upon the exercise of stock options outstanding under our 2013 Equity Incentive Plan, or our Prior Plan, as of June 30, 2020, at a weighted-average exercise price of \$1.51 per share;

[Table of Contents](#)

- 2,815,000 shares of our common stock issuable upon the exercise of stock options outstanding under our Prior Plan, granted between July 1 through September 30, 2020, at a weighted-average exercise price of \$6.84 per share;
- 7,924,000 additional shares of our common stock reserved for future issuance under our 2020 Incentive Award Plan, or our 2020 Plan, which will become effective in connection with this offering, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under our 2020 Plan; and
- 1,187,000 additional shares of our common stock that will become available for future issuance under our 2020 Employee Stock Purchase Plan, or our 2020 ESPP, which will become effective in connection with this offering, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under our 2020 ESPP.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 57,932,090 shares of our common stock, which will occur in connection with the closing of this offering;
- no exercise by the underwriters of their option to purchase additional shares of our common stock; and
- the filing of our restated certificate of incorporation.

Summary Consolidated Financial Data

The following tables summarize our consolidated financial data as of the dates indicated and for the periods then ended. We have derived the consolidated statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2018 (except for the pro forma net loss per share and the pro forma share information) from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The summary consolidated statements of operations data presented below for the six months ended June 30, 2020 and 2019 and the summary consolidated balance sheet data as of June 30, 2020 have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited consolidated financial information in those statements. In the opinion of management, the unaudited data reflect all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and our results for any interim period are not necessarily indicative of results that may be expected for any full year. You should read the following summary financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and the information in the sections titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Six Months Ended June 30,		Years Ended December 31,	
	2020	2019	2019	2018
(in thousands, except share and per share data) (unaudited)				
Statement of Operations and Comprehensive Loss Data				
Operating expenses:				
Research and development	\$ 10,576	\$ 4,270	\$ 10,170	\$ 6,675
General and administrative	3,472	1,820	4,438	2,802
Total operating expenses	14,048	6,090	14,608	9,477
Loss from operations	(14,048)	(6,090)	(14,608)	(9,477)
Interest income and other, net	67	343	574	413
Net loss and comprehensive loss	\$ (13,981)	\$ (5,747)	\$ (14,034)	\$ (9,064)
Net loss per share attributable to common stockholders - basic and diluted(1)	\$ (1.39)	\$ (0.57)	\$ (1.39)	\$ (0.90)
Weighted-average common shares outstanding - basic and diluted(1)	10,093,689	10,091,100	10,091,100	10,039,392
Pro forma net loss per share attributable to common stockholders - basic and diluted (unaudited)(2)	\$ (0.30)		\$ (0.32)	
Pro forma weighted-average common shares outstanding - basic and diluted (unaudited)(2)	47,292,517		43,736,547	

(1) For details on the calculation of our basic and diluted net loss per share attributable to common stockholders see Notes 10 and 11 to our unaudited and audited consolidated financial statements, respectively, included elsewhere in this prospectus.

(2) For details on the calculation of our pro forma basic and diluted net loss per share attributable to common stockholders see Notes 10 and 11 to our unaudited and audited consolidated financial statements, respectively, included elsewhere in this prospectus.

(in thousands)	As of June 30, 2020		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
Balance Sheet Data			
Cash and cash equivalents	\$ 115,792	\$ 573,292	\$ 849,092
Working capital(3)	111,392	218,892	494,692
Total assets	119,745	577,245	853,045
Convertible preferred stock	175,745	—	—
Total stockholders' (deficit) equity	(63,127)	220,118	495,918

(1) The pro forma balance sheet data gives effect to (i) the Series D-1 closing, (ii) the Roche Upfront Payment and (iii) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 57,932,090 shares of common stock, which will occur in connection with the closing of this offering and the filing of our restated certificate of incorporation.

(2) Reflects the pro forma adjustments described in footnote (1) above and the issuance and sale of shares of common stock in this offering at the initial public offering price of \$24.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities.

RISK FACTORS

You should carefully consider the risks and uncertainties described below, as well as the other information in this prospectus, including our financial statements and the related notes and “Management’s Discussion and Analysis of Results of Operations and Financial Condition,” before making an investment in our common stock. 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. This prospectus also contains forward-looking statements that involve risks and uncertainties. See “Special Note Regarding Forward-Looking Statements.” 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. We are conducting a Phase 2 clinical trial of AT-527 in hospitalized patients with moderate COVID-19 and at least one risk factor for complications related to COVID-19. 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. For example, we have allocated certain resources that could be used to develop AT-787 for the treatment of chronic hepatitis C, or HCV, to prioritize development of AT-527 for the treatment of 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. In addition, we anticipate announcing topline data from our Phase 2 trial after the expected closing of this offering. Our Phase 2 trial is subject to the risks related to clinical development discussed in this “Risk Factors” section. If the topline data are not supportive of further development of AT-527 as a treatment for COVID-19 or the market has a negative reaction to the topline 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 COVID-19 pandemic is uncertain. 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 another treatment for COVID-19 is 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 COVID-19 treatments. 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, or 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

[Table of Contents](#)

may enter into agreements with, and make payments to, contract manufacturing organizations, or CMOs, 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 our CMOs we will be able to meet any commercial demand for AT-527. If 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 will need to rapidly establish and build sales and marketing capabilities prior to obtaining approval to market AT-527. 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. has recently come under scrutiny regarding its pricing of remdesivir, after having donated its 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 severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, the virus that causes COVID-19, and any treatment we may develop could face significant competition. Many of these companies, which include large pharmaceutical companies, have greater resources for development and established commercialization capabilities. These companies may develop treatments more rapidly or effectively than we do, may develop a treatment that becomes the standard of care, may develop a treatment at a lower cost, or may be more successful at commercializing an approved treatment, all of which could adversely impact our business. As a result, 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.

COVID-19 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 have caused widespread disruption in business operations and economic activity. Governmental authorities around the world have 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 led 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, contract research organizations, or 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 HCV was paused until the clinical trial sites are able to re-open and we elect to resume patient enrollment, which has not yet occurred. Certain countries, including the United States, have begun the process of re-opening. However, any re-opening could take a significant amount of time, require additional resources to implement social-distancing and other preventive measures, or may not be successful.

[Table of Contents](#)

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.

COVID-19 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.

[Table of Contents](#)

For example, our HCV program has been delayed until the clinical trial sites conducting our Phase 1/2A trial are able to re-open and resume enrollment, 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 filings will likely be negatively impacted, which would adversely affect and delay our ability to obtain 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 symptoms, progression, and spread 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 financial condition.

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 losses since inception and expect to incur significant additional losses for the foreseeable future. We have no products that have generated any commercial revenue and we may never achieve or maintain profitability.

We have incurred significant operating losses since our inception, including operating losses of \$9.5 million, \$14.6 million and \$14.0 million for the years ended December 31, 2018 and 2019 and the six months ended June 30, 2020, respectively. As of June 30, 2020, we had an accumulated deficit of \$68.2 million. 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.

[Table of Contents](#)

We expect to continue to incur significant additional operating losses 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. 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, or 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 achieve or maintain profitability. Our expenses will also increase substantially if or as we:

- progress our ongoing clinical trial or initiate additional clinical trials of our most advanced product candidate, AT-527, including our ongoing Phase 2 clinical trial for the treatment of patients with moderate COVID-19;
- advance the development of our product candidates, including our Phase 2 clinical trial of AT-527, commencing a Phase 1/2A clinical trial of AT-527 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, AT-934 and other product candidates for the treatment of respiratory syncytial virus, or 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;
- 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;
- incur additional legal, accounting and other expenses in operating our business; and
- operate as a public company.

[Table of Contents](#)

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 losses and negative cash flows for the foreseeable future. These operating losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

The amount of future losses and when, if ever, we will achieve 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 achieve 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.

Even if we consummate this offering, 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 and AT-787, to initiate the clinical development of AT-752, for future clinical trials for our other product candidates and to continue to identify new product candidates.

Even after the consummation of this offering, we will continue to need additional capital beyond the proceeds of this offering 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.

As of June 30, 2020, we had cash and cash equivalents of \$115.8 million. We estimate that our net proceeds from this offering will be approximately \$275.8 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The net proceeds from this offering and our existing cash and cash equivalents will not be sufficient to fund all of our efforts that we plan to undertake.

Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, 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

[Table of Contents](#)

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.

Raising additional capital may cause additional dilution to our stockholders, including purchasers of common stock in this offering, 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

[Table of Contents](#)

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.

We have not generated any revenue and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. Prior to the execution of the Roche License Agreement, we have not generated any revenue and do not expect to generate significant 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. Other than AT-527, AT-787 and AT-752, our product candidates are in the preclinical stages of development and will require additional preclinical studies and 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-, or IND-, enabling studies and successfully submit INDs or comparable applications to allow us to initiate additional clinical trials of AT-527, AT-787 and AT-752, and initiate clinical trials for any future 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;

Table of Contents

- 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, or 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 achieve profitability soon after generating product sales, if ever. 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, 2019, we had U.S. federal net operating loss carryforwards, or NOLs, of \$49.3 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 \$21.8 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, 2019, we had state NOLs of \$49.2 million, which may be available to offset future taxable income, if any, and begin to expire in 2033. As of December 31, 2019, we also had federal and state research and development credit carryforwards of \$0.35 million and \$0.14 million, respectively, which begin to expire in 2033. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or 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 in connection with or after this offering, 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 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

[Table of Contents](#)

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 these 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 of these product candidates may be delayed, which may affect our ability to successfully commercialize any 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 any products to treat COVID-19, HCV, RSV, dengue, or any other diseases which our current or future product candidates are designed 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 such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Nor can we be certain that, if approved, the safety and efficacy profile of these 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. For example there are currently no drugs approved by the FDA for the treatment of COVID-19, and therefore the nature and amount of clinical and other data that may be required for the FDA to approve AT-527 for the treatment of moderate COVID-19 remains unclear. Although we believe that our ongoing and planned Phase 2 trials of AT-527 in moderate COVID 19, if successful, may enable us to submit an NDA seeking accelerated approval of AT-527 for the treatment of moderate COVID-19, we have not yet discussed potential registration pathways with the FDA, and 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

[Table of Contents](#)

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, or 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

[Table of Contents](#)

completed any late-stage or pivotal clinical trials for any of our product candidates. We cannot guarantee that any of our 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, or IRB, 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, or 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;

Table of Contents

- 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, or DSMB, for such trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA 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 have for our COVID-19 and HCV product candidates and expect to do for our dengue 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

[Table of Contents](#)

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, 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;

[Table of Contents](#)

- 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.

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;

[Table of Contents](#)

- 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.

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

[Table of Contents](#)

- 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. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our 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 data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

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;

[Table of Contents](#)

- 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, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. For example, we have allocated certain resources that could be used to develop AT-787 for the treatment of chronic HCV to prioritize development of AT-527 for the treatment of COVID-19. If we are unable to identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

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.

[Table of Contents](#)

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 non-expedited 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 candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling,

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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. 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.

We also expect that operating as a public company 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,

[Table of Contents](#)

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, intensity and sophistication of attempted attacks and intrusions from around the world have increased. 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 cyber criminals 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. 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, or 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

[Table of Contents](#)

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, or 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;

[Table of Contents](#)

- 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, President Trump signed into law federal tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act, 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. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review 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 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% reductions from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. 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

[Table of Contents](#)

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 lose any marketing approval that we may have obtained 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, or 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

[Table of Contents](#)

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, or 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 Federal Food, Drug and Cosmetic Act, or 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.

[Table of Contents](#)

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 and the European Economic Area, or EEA, Regulation 2016/679, known as the General Data Protection Regulation, or 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, or 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. 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 implements more stringent operational requirements than its predecessor legislation. For example, the GDPR applies extraterritorially, 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

[Table of Contents](#)

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. Additionally, following the United Kingdom's withdrawal from the EU, which is commonly referred to as Brexit, beginning in 2021 we will have to comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine up to the greater of €20 million or 4% of global turnover for violations. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. 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, 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 classified 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, or 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, including the CCPA, 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

[Table of Contents](#)

information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the 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 of treatments for COVID-19 (or vaccines for SARS-CoV-2), HCV, dengue and RSV.

[Table of Contents](#)

There are several approved drugs 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

[Table of Contents](#)

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 market and sell the product.

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. We are evaluating the opportunities for the development and commercialization of our 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;

[Table of Contents](#)

- 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 countries 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 related litigation and related litigation;

[Table of Contents](#)

- 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, and the inability to commercialize any product candidate;
- 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 our Dependence on Third Parties and Manufacturing

We will rely on third parties for the manufacture of raw 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 raw 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. We do not have a long-term agreement with any of the third-party manufacturers we currently use to provide preclinical and clinical raw 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;

Table of Contents

- 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 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 candidates, 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 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.

[Table of Contents](#)

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. 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 all 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, 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 raw material 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 2 clinical trial for AT-527 for the treatment of COVID-19, our Phase 1/2A clinical trial of AT-787 for the treatment of HCV and our IND-enabling studies for AT-752, and we expect to rely on third parties to conduct future clinical trials and preclinical studies for our product candidates. 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

[Table of Contents](#)

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 an exclusive license for certain development and commercialization rights related to AT-527 outside of the United States to Roche. 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;

Table of Contents

- 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. We may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of our 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

[Table of Contents](#)

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 projects, 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 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 and biological materials, by our manufacturers. Our manufacturers 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' 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, AT-527, AT-281, 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.

[Table of Contents](#)

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

[Table of Contents](#)

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, or 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, or 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

[Table of Contents](#)

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, or 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

[Table of Contents](#)

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; Hoffman-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

[Table of Contents](#)

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, or 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, or 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 New Drug Application, or 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, or 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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

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.

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, or

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, or 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.

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,

[Table of Contents](#)

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 regulatory approval, clinical trial management 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.

[Table of Contents](#)

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 September 30, 2020, we had 19 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 a number of common stock options. 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 described herein. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

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 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.

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

[Table of Contents](#)

economic growth, increases in unemployment rates and uncertainty about economic stability. For example, the COVID-19 pandemic has resulted in a 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.

On January 31, 2020, the United Kingdom formally withdrew from the European Union. The potential impact of the withdrawal of the United Kingdom will vary significantly depending on the exit route that is negotiated and agreed between the European Union and the United Kingdom during the transition period, which is due to end December 31, 2020. For example, companies in the United Kingdom could lose access to the benefits of certain EU directives (such as the interest and royalties directive and the parent-subsidiary directive), which apply only to arrangements concerning EU Member States.

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 and this Offering

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations with the underwriters. Although we have been approved to have our common stock listed on the Nasdaq Global Select Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the

[Table of Contents](#)

market price for the shares, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be 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 or above the initial public offering price. 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;

Table of Contents

- 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 and elsewhere in this prospectus.

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. If the market price of our common shares after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. 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.

If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. To the extent shares subsequently are issued under outstanding options, you will incur further dilution. Based on the initial public offering price of \$24.00 per share, you will experience immediate dilution of \$17.87 per share as of June 30, 2020, representing the difference between our pro forma as adjusted net tangible book value per share, after giving effect to this offering, and the assumed initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately 51% of the aggregate price paid by all purchasers of our stock but will own only approximately 15% of our common stock outstanding after this offering.

[Table of Contents](#)

This dilution is due to our investors who purchased shares of our common stock prior to this offering, having paid substantially less when they purchased their shares of common stock than the price offered to the public in this offering. To the extent that outstanding stock options or warrants are exercised, there will be further dilution to new investors. As a result of the dilution to investors purchasing shares of common stock in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see the section entitled "Dilution."

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. We anticipate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents, the proceeds from the Series D-1 Closing and the Roche Upfront Payment to advance (i) the development of our AT-527 program for the treatment of COVID-19 through Phase 3 clinical trials; (ii) the development of our AT-787 program for the treatment of HCV through the completion of our planned Phase 2 clinical trial; (iii) the development of our AT-752 program for the treatment of dengue through the completion of our planned Phase 2 clinical trial; (iv) the development of AT-889, AT-934 and other product candidates for the treatment of RSV through the completion of our planned Phase 2 clinical trial; and (v) the remainder to fund the continued expansion of our platform technology, preclinical studies for research stage programs, working capital, and other general corporate purposes. See "Use of Proceeds." However, our use of these proceeds may differ substantially from our current plans. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Our principal stockholder 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.

Upon the closing of this offering, based on the number of shares outstanding as of September 30, 2020, assuming the conversion of all outstanding shares of preferred stock into common stock and after giving effect to the Series D-1 Closing, our executive officers, directors, and 5% stockholders will beneficially own approximately 38.5% of our common shares after this offering, and not accounting for any shares of common stock purchased in this offering by certain of our existing stockholders (or their affiliates). Therefore, after this offering, 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.

Participation in this offering by our existing stockholders and their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and principal stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, 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. After this offering, we will have 80,741,937 outstanding shares of common stock based on the number of shares outstanding as of September 30, 2020. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates or existing stockholders. The remaining shares are currently restricted as a result of securities laws or lock-up agreements (which may be waived, with or without notice, pursuant to the terms of such lock-up agreement), but will become eligible to be sold at various times beginning 180 days after this offering, unless held by one of our affiliates, in which case the resale of those securities will be subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended, or Rule 144. Moreover, after this offering, holders of an aggregate of 57,932,090 shares of our common stock will 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 or until the rights terminate pursuant to the terms of the stockholders' agreement between us and such holders. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

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 this offering, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common shares that are held by non-affiliates to exceed \$700 million as of the prior June 30th, 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:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- 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.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We

cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. 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.

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, 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, or 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 will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. 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. Upon becoming a public company, we will be 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 the later of the year following our first annual report required to be filed with the SEC or the date 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 will need to undertake 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.

Upon the closing of this offering, we will become 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.

[Table of Contents](#)

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 do not currently have, and may never obtain, research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who 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 restated bylaws, which will become effective upon the closing of this offering 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 could also limit the price that investors might be 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;

Table of Contents

- 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 will designate 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, which will become effective upon the closing of this offering, 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.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would 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

[Table of Contents](#)

appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future. See the “Dividend Policy” section of this prospectus for additional information.

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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements, including, but not limited to, statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management. These statements 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.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” “would” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this prospectus are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- our status as a development-stage company and our expectation to incur losses in the future;
- the effects of the COVID-19 pandemic on business operations, the initiation, development and operation of our clinical trials, and patient enrollment of our clinical trials;
- our future capital needs and our need to raise additional funds;
- the prospects of AT-527 and other product candidates, which are still in development;
- our expectations regarding the timing of data from our clinical trials for AT-527 and other product candidates;
- our ability to continuously build a pipeline of product candidates and develop and commercialize drugs;
- our unproven approach to antiviral treatments;
- our ability to enroll patients and volunteers in clinical trials, timely and successfully complete those trials and receive necessary regulatory approvals;
- our ability to establish our own manufacturing facilities and to receive or manufacture sufficient quantities of our product candidates;
- our ability to obtain, maintain, protect and enforce our intellectual property rights;
- federal, state, and foreign regulatory requirements, including FDA regulation of our product candidates;
- the timing of clinical trials and the likelihood of regulatory filings and approvals;
- developments relating to our competitors and our industry;

[Table of Contents](#)

- our ability to obtain and retain key executives and attract and retain qualified personnel; and
- our ability to successfully manage our growth.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement relating to this offering completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements in this prospectus by these cautionary statements.

MARKET AND INDUSTRY DATA

We obtained the market and industry data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. While we believe our internal company research as to such matters is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately \$275.8 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares from us is exercised in full, we estimate that our net proceeds will be approximately \$317.7 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

As of June 30, 2020, we had cash, and cash equivalents of \$115.8 million. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, the proceeds from the Series D-1 Closing and the Roche Upfront Payment, as follows:

- approximately \$300.0 million to fund the development of our AT-527 program for the treatment of COVID-19 through Phase 3 clinical trials;
- approximately \$60.0 million to fund the development of our AT-787 program for the treatment of HCV through the completion of our planned Phase 2 clinical trial;
- approximately \$40.0 million to fund the development of our AT-752 program for the treatment of dengue, through the completion of our planned Phase 2 clinical trial;
- approximately \$60.0 million to fund the development of AT-889, AT-934 and other product candidates for the treatment of RSV through the completion of our planned Phase 2 clinical trial; and
- the remainder to fund the continued expansion of our platform technology, preclinical studies for research stage programs, working capital, and other general corporate purposes.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates can be difficult and we anticipate that we will need additional funds to complete the development of any product candidates we identify. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from our ongoing clinical trial(s) or any clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering, and investors will be relying on our judgment regarding the application of the net proceeds.

Based on our planned use of the net proceeds from this offering and our current cash and cash equivalents, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through at least 2023. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources. See "Management's Discussion and Analysis of Financial Condition and Results of Operation—Liquidity and Capital Resources—Future Funding Requirements" and "Risk Factors—Risks Related to Our Financial Condition and Capital Requirement."

[Table of Contents](#)

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term and intermediate-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for the development, operation and expansion of our business and do not anticipate declaring or paying any dividends in the foreseeable future. The payments of dividends, if any, will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, business prospects, contractual arrangements, any limitations on payment of dividends present in our future debt agreements and other factors that our board of directors may deem relevant, and will be subject to the restrictions contained in any future financing instruments.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and total capitalization as of June 30, 2020, as follows:

- on an actual basis;
- on a pro forma basis to give effect to (i) the Series D-1 Closing, (ii) the Roche Upfront Payment, (iii) the filing of a certificate of amendment to our amended and restated certificate of incorporation and (iv) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 57,932,090 shares of common stock in connection with the closing of this offering and the filing of our restated certificate of incorporation; and
- on a pro forma as adjusted basis to further reflect our issuance and sale of shares of common stock in this offering at the initial public offering price of \$24.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our consolidated financial statements and the related notes appearing elsewhere in this prospectus, as well as the sections of this prospectus titled "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Description of Capital Stock."

	As of June 30, 2020		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
	(unaudited)		
Cash and cash equivalents	\$ 115,792	\$ 573,292	\$ 849,092
Convertible preferred stock, \$0.001 par value per share; 57,932,090 shares authorized, 48,958,829 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$ 175,745	—	
Stockholders' (deficit) equity:			
Preferred stock, \$0.001 par value per share; no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	
Common stock, \$0.001 par value per share; 80,529,575 shares authorized, 10,309,847 shares issued and outstanding, actual; 300,000,000 shares authorized, 68,241,937 shares issued and outstanding, pro forma; 300,000,000 shares authorized, 80,741,937 shares issued and outstanding, pro forma as adjusted	10	68	81
Additional paid-in capital	5,057	288,244	564,032
Accumulated deficit	(68,194)	(68,194)	(68,194)
Total stockholders' (deficit) equity	(63,127)	220,118	495,918
Total capitalization	\$ 112,618	\$ 220,118	\$ 495,918

[Table of Contents](#)

The number of shares in the table above excludes the following:

- 4,186,747 shares of common stock issuable upon exercise of options outstanding under our Prior Plan to purchase shares of our common stock outstanding as of June 30 , 2020, at a weighted-average exercise price of \$1.51 per share;
- 7,924,000 shares of common stock reserved for future issuance under our 2020 Plan, which will become effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2020 Plan; and
- 1,187,000 shares of common stock reserved for issuance under our 2020 ESPP, which will become effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2020 ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book deficit as of June 30, 2020 was \$(64.3) million, or \$(6.23) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets (total assets less deferred offering costs) less our total liabilities and convertible preferred stock, which is not included within our stockholders' (deficit) equity. Historical net tangible book value per share represents historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding as of June 30, 2020.

Our pro forma net tangible book value as of June 30, 2020 was \$219.0 million, or \$3.21 per share of our common stock. Pro forma net tangible book value (deficit) represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the Series D-1 Closing, (ii) the Roche Upfront Payment and (iii) the automatic conversion of all of the shares of our convertible preferred stock outstanding into an aggregate of 57,932,090 shares of common stock upon the completion of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of June 30, 2020, after giving effect to the pro forma adjustments described above.

After giving further effect to receipt of the net proceeds from our issuance and sale of 12,500,000 shares of common stock in this offering at the initial public offering price of \$24.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2020 would have been \$494.8 million, or \$6.13 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$2.92 to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value per share of \$17.87 to new investors purchasing common stock in this offering. Dilution per share to new investors purchasing common stock in this offering is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors.

The following table illustrates this dilution on a per share basis:

Initial public offering price per share		\$	24.00
Historical net tangible book value (deficit) per share as of June 30, 2020		\$(6.23)	
Increase per share attributable to the pro forma adjustments described above		9.44	
Pro forma net tangible book value (deficit) per share as of June 30, 2020		3.21	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering		2.92	
Pro forma as adjusted net tangible book value per share after this offering		\$	6.13
Dilution per share to new investors purchasing shares in this offering		\$	17.87

If the underwriters exercise their option to purchase additional shares of common stock in this offering in full, the pro forma as adjusted net tangible book value per share after this offering would be \$6.50 per share, and the dilution in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering would be \$17.50 per share, in each case based on the initial public offering price of \$24.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

[Table of Contents](#)

The following table summarizes, on a pro forma as adjusted basis, as of June 30, 2020, the number of shares of common stock purchased from us on an as-converted to common stock basis, the total consideration paid, or to be paid and the weighted-average price per share paid, or to be paid, by existing stockholders and by new investors in this offering at the initial public offering price of \$24.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Weighted-Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	
Existing stockholders before this offering	68,241,937	85%	\$286,024,000	49%	\$ 4.19
Investors participating in this offering	12,500,000	15%	300,000,000	51%	\$ 24.00
Total	80,741,937	100%	\$586,024,000	100%	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering and no purchase of shares by any existing stockholders in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to approximately 1.9% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to approximately 1.9% of the total number of shares outstanding after this offering.

The above tables and discussion exclude the following:

- 4,186,747 shares of common stock issuable upon exercise of options outstanding under our Prior Plan to purchase shares of our common stock outstanding as of June 30, 2020, at a weighted-average exercise price of \$1.51 per share;
- 7,924,000 shares of common stock reserved for future issuance under our 2020 Plan, which will become effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2020 Plan; and
- 1,187,000 shares of common stock reserved for issuance under our 2020 ESPP, which will become effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2020 ESPP.

To the extent that any outstanding options are exercised or new options are issued under the equity benefit plans, or we issue additional shares of common stock or other securities convertible into or exercisable or exchangeable for shares of our capital stock in the future, there will be further dilution to investors participating in this offering.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables summarize our selected consolidated financial data for the periods and as of the dates indicated. We have derived our selected consolidated statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2018 (except for the pro forma net loss per share and the pro forma share information), and the consolidated balance sheet data as of December 31, 2019 and 2018, from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The consolidated statements of operations data for the six months ended June 30, 2020 and 2019 and the consolidated balance sheet data as of June 30, 2020 are derived from our unaudited consolidated financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and our results for any interim period are not necessarily indicative of results that may be expected for any full year. You should read the financial and other data below in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	Six Months Ended June 30,		Years Ended December 31,	
	2020	2019	2019	2018
(in thousands, except share and per share amounts) (unaudited)				
Statement of Operations and Comprehensive Loss Data				
Operating expenses:				
Research and development	\$ 10,576	\$ 4,270	\$ 10,170	\$ 6,675
General and administrative	3,472	1,820	4,438	2,802
Total operating expenses	14,048	6,090	14,608	9,477
Loss from operations	(14,048)	(6,090)	(14,608)	(9,477)
Interest income and other, net	67	343	574	413
Net loss and comprehensive loss	\$ (13,981)	\$ (5,747)	\$ (14,034)	\$ (9,064)
Net loss per share attributable to common stockholders - basic and diluted(1)	\$ (1.39)	\$ (0.57)	\$ (1.39)	\$ (0.90)
Weighted-average common shares outstanding - basic and diluted(1)	10,093,689	10,091,100	10,091,100	10,039,392
Pro forma net loss per share attributable to common stockholders - basic and diluted (unaudited)(2)	\$ (0.30)		\$ (0.32)	
Pro forma weighted-average common shares outstanding - basic and diluted (unaudited)(2)	47,292,517		43,736,547	

(1) For details on the calculation of our basic and diluted net loss per share attributable to common stockholders see Notes 10 and 11 to our unaudited and audited consolidated financial statements, respectively, included elsewhere in this prospectus.

(2) For details on the calculation of our pro forma basic and diluted net loss per share attributable to common stockholders see Notes 10 and 11 to our unaudited and audited consolidated financial statements, respectively, included elsewhere in this prospectus.

[Table of Contents](#)

	<u>As of</u> <u>June 30,</u> <u>2020</u>	<u>As of December 31,</u> <u>2019</u> <u>2018</u>	
	(unaudited)	(in thousands)	
Balance Sheet Data			
Cash and cash equivalents	\$ 115,792	\$ 21,661	\$ 34,492
Working capital(1)	111,392	19,475	32,938
Total assets	119,745	22,073	34,861
Total liabilities	7,127	2,530	1,908
Convertible preferred stock	175,745	69,114	69,114
Accumulated deficit	(68,194)	(54,213)	(40,179)
Total stockholders' deficit	(63,127)	(49,571)	(36,161)

(1) We define working capital as current assets less current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this prospectus. See "Special Note Regarding Forward-Looking Statements."

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 prodrugs for difficult to treat, life-threatening viral infections, including SARS-CoV-2, the virus that causes COVID-19, HCV, dengue virus, and RSV.

Since our formation in July 2012, we have devoted substantially all of our resources to developing our product candidates. We have incurred significant operating losses to date. Our net loss was \$14.0 million and \$9.1 million for the years ended December 31, 2019 and 2018, respectively. Our net loss was \$14.0 million for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of \$68.2 million. We expect that our operating expenses 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, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company.

We do not have any product candidates approved for sale and have not generated any revenue since inception. We have funded our operations primarily from the sale and issuance of convertible preferred stock. As of June 30, 2020, we had cash and cash equivalents of \$115.8 million. We believe that our available cash and cash equivalents will be sufficient to fund our planned operations through at least 2023.

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 CROs and CMO, 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 significant expenses and operating losses 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;

[Table of Contents](#)

- re-initiate clinical development of AT-787 for the treatment of HCV;
- continue IND-enabling activities and commence the planned clinical development activities for product candidates for the treatment of dengue;
- continue activities to discover, validate and develop 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; and
- incur additional costs associated with operating as a public company upon the closing of this offering.

Components of Results of Operations

Revenue

Through September 30, 2020, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. We will begin recognizing revenue related to the Roche License Agreement beginning on the effective date of the agreement. 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 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 basis as they are deployed across multiple programs. The following table summarizes our external research and development expenses by indication and internal research and development expenses:

	Six Months Ended		Years Ended December 31,	
	June 30,			
	2020	2019	2019	2018
	(in thousands)			
HCV external costs	\$ 1,683	\$ 2,353	\$ 5,837	\$ 2,979
COVID-19 external costs	5,487	—	—	—
Dengue external costs	1,049	207	768	297
RSV external costs	660	656	1,379	1,790
Internal research and development costs	1,697	1,054	2,186	1,609
Total research and development costs	\$ 10,576	\$ 4,270	\$ 10,170	\$ 6,675

[Table of Contents](#)

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 following this offering and 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 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 Six Months Ended June 30, 2020 and 2019

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

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Operating expenses:			
Research and development	\$ 10,576	\$ 4,270	\$ 6,306
General and administrative	3,472	1,820	1,652
Total operating expenses	14,048	6,090	7,958
Loss from operations	(14,048)	(6,090)	(7,958)
Interest income and other, net	67	343	(276)
Net loss	\$ (13,981)	\$ (5,747)	\$ (8,234)

Research and Development Expenses

Research and development expenses increased by \$6.3 million from \$4.3 million for the six months ended June 30, 2019 to \$10.6 million for the six months ended June 30, 2020. The increase in research and

[Table of Contents](#)

development expenses was primarily due to the advancement of product candidates for the treatment of COVID-19 and dengue and reflected an increase in expenses incurred related to CRO and CMO services of \$5.7 million and a \$0.6 million increase in consulting, payroll and personnel-related expenses, including salaries and bonuses, benefits and stock-based compensation expense for our research and product development employees.

General and Administrative Expenses

General and administrative expenses increased by \$1.7 million from \$1.8 million for the six months ended June 30, 2019 to \$3.5 million for the six months ended June 30, 2020. The increase in general and administrative expenses was primarily due to the expansion of our organization and reflected an increase in professional fees of \$1.1 million; payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense, of \$0.3 million; a license termination fee of \$0.2 million; and an increase in other general and administrative expenses \$0.1 million.

Interest Income and Other, Net

Interest income and other, net, decreased by \$0.3 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, primarily due to lower average cash and cash equivalents balances and lower interest rates.

Comparison of the Years Ended December 31, 2019 and 2018

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

	Years Ended December 31,		Change
	2019	2018	
	(in thousands)		
Operating expenses:			
Research and development	\$ 10,170	\$ 6,675	\$ 3,495
General and administrative	4,438	2,802	1,636
Total operating expenses	14,608	9,477	5,131
Loss from operations	(14,608)	(9,477)	(5,131)
Interest income and other, net	574	413	161
Net loss	\$ (14,034)	\$ (9,064)	\$ (4,970)

Research and Development Expenses

Research and development expenses increased by \$3.5 million from \$6.7 million for the year ended December 31, 2018 to \$10.2 million for the year ended December 31, 2019. The increase in research and development expenses was primarily due to the advancement of preclinical, manufacturing and clinical expense of \$2.9 million related to product candidates for the treatment of HCV and an increase of \$0.5 million in consulting, payroll and personnel-related expenses, including salaries and bonuses, benefits and stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses increased by \$1.6 million from \$2.8 million for the year ended December 31, 2018 to \$4.4 million for the year ended December 31, 2019. The increase in general and administrative expenses was primarily due to the expansion of our organization and reflected an increase of \$0.5 million in payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense; and an increase in other general and administrative expenses, including legal and accounting of \$1.1 million.

Interest Income and Other, Net

Interest income and other, net increased by \$0.2 million for year ended December 31, 2019 from the year ended December 31, 2018 due higher average cash and cash equivalent balances during the year.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation in 2012 through June 30, 2020, we have funded our operations with an aggregate of \$178.1 million in gross cash proceeds from the sale of convertible preferred stock. As of June 30, 2020, we had cash and cash equivalents of \$115.8 million. The Series D investors were obligated to purchase \$35.8 million of Series D-1 convertible preferred stock upon the achievement of a clinical development milestone as defined in the agreement. In addition, the investors have the option to purchase up to \$71.7 million of Series D-1 convertible preferred stock following the aforementioned clinical development milestone and receipt of certain additional preclinical data. Unless previously exercised, the option to purchase the shares of Series D-1 convertible preferred stock would terminate (i) eight days after the filing of the registration statement relating to this offering or (ii) in the event that the clinical development milestone discussed above occurs after the filing of the registration statement relating to this offering and prior to the consummation of the offering, upon the consummation of the offering. In October 2020, the Series D investors exercised their right and purchased the fully authorized 8,973,261 shares of the Series D-1 convertible preferred stock at a purchase price of \$11.98 per share for an aggregate purchase price of \$107.5 million.

In addition, the Company expects to receive the \$350 million Roche Upfront Payment in November 2020.

Future Funding Requirements

We have incurred net losses since our inception. For the years ended December 31, 2019 and 2018, we incurred net losses of \$14.0 million and \$9.1 million, respectively. For the six months ended June 30, 2020 we incurred a net loss of \$14.0 million and expect to incur substantial additional losses in future periods. As of June 30, 2020, we had an accumulated deficit of \$68.2 million. Based on our current business plan, we believe that our existing cash and cash equivalents including the proceeds from the Series D-1 Closing, the Roche Upfront Payment and the proceeds from the offering will be sufficient to fund our planned operations at least through 2023.

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates or enter into collaborative agreements with third parties, and we do not know when, or if, either will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses 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, following the completion of this offering, we expect to incur additional costs associated with operating 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 private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. We anticipate that we will 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;

Table of Contents

- 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 establish and maintain 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 the section of this prospectus titled "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:

	Six Months Ended		Years Ended December 31,	
	2020	2019	2019	2018
	(in thousands)			
Net cash (used in) provided by:				
Operating activities	\$ (12,306)	\$ (5,207)	\$ (12,814)	\$ (7,908)
Investing activities	(6)	—	(2)	(12)
Financing activities	106,443	—	(15)	27,483
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 94,131	\$ (5,207)	\$ (12,831)	\$ 19,563

Cash Flows from Operating Activities

Net cash used in operating activities was \$12.3 million for the six months ended June 30, 2020. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates, resulting in a net loss of \$14.0 million, offset by stock based compensation of \$0.4 million. Additional uses of cash during the period included an increase in prepaid expenses and other current assets of \$2.4 million offset by an increase in accounts payable and accrued expenses of \$3.7 million.

Net cash used in operating activities was \$5.2 million for the six months ended June 30, 2019. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of \$5.7 million, offset by stock based compensation of \$0.3 million. Additional uses of cash during the period included an increase in accounts payable and accrued expenses of \$0.2 million.

Net cash used in operating activities was \$12.8 million for the year ended December 31, 2019. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of \$14.0 million, offset by stock based compensation of \$0.6 million and increases in accounts payable and accrued expenses of \$0.6 million.

Net cash used in operating activities was \$7.9 million for the year ended December 31, 2018. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of \$9.1 million, offset by stock based compensation of \$0.4 million and increases and accrued expenses of \$0.7 million.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$106.4 million for the six months ended June 30, 2020, which consisted primarily of \$106.6 million of net proceeds from the sale of Series D convertible preferred stock partially offset by payment of deferred offering costs of \$0.2 million.

Net cash provided by financing activities was \$27.5 million for the year ended December 31, 2018, which consisted primarily of \$27.4 million of net proceeds from the sale of Series C convertible preferred stock.

Contractual Obligations and Commitments

We lease our office space under a non-cancelable operating lease in Boston, Massachusetts, that expires in July 2022. The following table summarizes our contractual obligations as of December 31, 2019:

	Payments Due by Period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Operating lease obligations	\$ 335	\$ 540	\$ —	\$ —	\$ 875

We enter into contracts in the normal course of business with third-party contract organizations 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.

The table above also does not include potential milestone and success fees that we may be required to pay under agreements we have entered into with certain consultants. We have an agreement with a consultant that requires payment of a success fee of up to a maximum of \$1.75 million if a business development transaction that meets or exceeds certain thresholds is executed on or before December 31, 2020. We also have 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. We have not included such potential obligations in the table above because they are contingent upon the occurrence of future events and the timing and likelihood of such potential obligations are not known with certainty.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or 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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued Research and Development

We have entered into various agreements with CMOs and CROs. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to CMOs and CROs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We use a fair value-based method to account for all stock-based compensation arrangements with employees and non-employees, including stock options and stock awards. The fair value of the option granted is recognized on a straight-line basis over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period, which usually is the vesting period. In determining fair value of the stock options granted, we use the Black-Scholes model, which requires the input of subjective assumptions. These assumptions include: estimating the fair market value of the common stock, estimating the length of time employees will retain their vested stock options before exercising them (expected term), the estimated volatility of our common stock price over the expected term (expected volatility), risk-free interest rate and expected dividends. See Note 9 to our audited and unaudited consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted during the six months ended June 30, 2020 and the years ended December 31, 2019 and 2018, respectively. Estimating the fair value of our common stock involves significant judgement and the use of estimates.

Estimating the Fair Value of Common Stock

We are required to estimate the fair value of the common stock underlying our share-based awards when performing the fair value calculations using the Black-Scholes option pricing model. Because our common stock is not currently publicly traded, the fair value of the common stock underlying our stock options has been determined on each grant date by our board of directors, with input from management, considering the most recently available third-party valuation of our common shares. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the estimated fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant.

In the absence of a public trading market for our common stock, on each grant date, we develop an estimate of the fair value of our common stock based on valuations from an independent third-party valuation firm using information known to us on the date of grant, a review of any recent events and their potential impact on the estimated fair value per share of the common stock.

The third-party valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid.

The assumptions used to determine the estimated fair value of our common stock are based on numerous objective and subjective factors, combined with management judgment, including:

- external market conditions affecting the pharmaceutical and biotechnology industry and trends within the industry;
- our stage of development and business strategy;
- the rights, preferences and privileges of our redeemable convertible preferred stock relative to those of our common stock;
- the prices at which we sold shares of our redeemable convertible preferred stock;
- our financial condition and operating results, including our levels of available capital resources;
- the progress of our research and development efforts;
- equity market conditions affecting comparable public companies; and
- general U.S. market conditions and the lack of marketability of our common stock.

[Table of Contents](#)

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, we considered the following methods:

- *Option Pricing Method.* Under the option pricing method, or OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- *Probability-Weighted Expected Return Method.* The probability-weighted expected return method, or PWERM, is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

Based on our early stage of development and other relevant factors, we determined that OPM method as well as a hybrid approach of the OPM and the PWERM methods were the most appropriate methods for allocating our enterprise value to determine the estimated fair value of our common stock. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of our common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

Following the completion of this offering, the fair value of our common stock will be based on the closing quoted market price of our common stock.

The following table presents the grant dates, number of underlying shares of common stock and the per share exercise prices of stock options granted between January 1, 2018 and the date of this prospectus, along with the fair value per share utilized to calculate stock-based compensation:

Grant date	Number of shares	Exercise price of award per share⁽¹⁾	Fair value of common stock per share on grant date	Per share estimated fair value of award⁽²⁾
April 6, 2018	75,000	\$ 1.53	\$ 1.53	\$ 0.94
December 14, 2018	935,000	\$ 1.43	\$ 1.43	\$ 0.71
July 31, 2019	116,891	\$ 1.43	\$ 1.43	\$ 0.87
September 20, 2019	75,000	\$ 1.43	\$ 1.43	\$ 0.66
December 13, 2019	899,742	\$ 1.85	\$ 1.85	\$ 1.26
April 3, 2020	293,861	\$ 1.57	\$ 1.57	\$ 1.08
August 3, 2020	1,490,000	\$ 6.83	\$ 6.83	\$ 4.96
August 17, 2020	1,005,000	\$ 6.84	\$ 6.84	\$ 5.08
August 26, 2020	620,000	\$ 6.85	\$ 6.85	\$ 5.09
October 1, 2020	160,000	\$ 8.02	\$ 8.02	\$ 5.98

(1) The exercise price of award per share represents the fair value of our common stock on the date of grant, as determined by our board of directors, after taking into account our most recently available contemporaneous valuation of our common stock

(2) The per share estimated fair value of award represents the weighted average fair value of options as estimated at the date of grant using the Black-Scholes option pricing model.

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 (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) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Recently Issued Accounting Pronouncements

See the section titled "Summary of Significant Accounting Policies—Recently Issued Accounting Pronouncements" in Note 2 to our consolidated financial statements included elsewhere in this prospectus for additional information.

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 June 30, 2020, we had cash and cash equivalents of \$115.8 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

[Table of Contents](#)

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.

BUSINESS

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, or ssRNA, viruses, which are a prevalent cause of severe viral diseases. Currently, we are focused on the development of orally available, potent, and selective nucleotide prodrugs for difficult-to-treat, life-threatening viral infections, including severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, the virus that causes COVID-19, hepatitis C virus, or HCV, dengue virus, and respiratory syncytial virus, or RSV. We believe our team's expertise from decades of developing innovative antiviral treatments uniquely positions us to advance medicines that have the potential to cure some of the world's most severe viral diseases by inhibiting the enzymes central to viral replication.

Over the last 40 years, nucleoside and nucleotide, or together, nucleos(t)ide, analogs have been developed to mimic naturally occurring nucleic acids and block viral replication by inhibiting enzymes involved in RNA and DNA viral growth cycles. Nucleos(t)ide analogs have become the backbone of therapies that treat life-threatening viral infections, including human immunodeficiency virus, or HIV, hepatitis B, or HBV, and HCV. Our expertise has allowed us to develop a proprietary platform, which facilitates the development of product candidates that combine unique purine nucleotide scaffolds with a novel double prodrug strategy. We believe that utilizing this double prodrug moiety approach allows us to maximize formation of the active metabolite, potentially resulting in oral antiviral product candidates that are selective for and highly effective at preventing replication of ssRNA viruses while avoiding toxicity to host cells. We have produced a large library of nucleoside and nucleotide prodrugs specifically designed to target viral RNA-dependent RNA polymerase, or RdRp, a key enzyme that is encoded in the viral genome. All ssRNA viruses, including SARS-CoV-2 and HCV, depend on RdRp for replication and transcription and, since viral RdRp is not present in the host cell, RdRp is an ideal target to inhibit virus replication.

Our lead product candidate, AT-527, is an orally administered, novel antiviral agent for the treatment of patients infected with SARS-CoV-2, which causes COVID-19. AT-527 has been shown to be well tolerated and highly effective against HCV in Phase 2 clinical trials with HCV-infected subjects and this highly selective antiviral activity has now been demonstrated *in vitro* against SARS-CoV-2. The RdRps in SARS-CoV-2 support the transcription and replication of the approximately 30,000-nucleotide RNA viral genome. The RdRps in SARS-CoV-2 and severe acute respiratory syndrome coronavirus 1, or SARS-CoV, the virus that causes severe acute respiratory disease, are the largest and most complex RdRps among RNA viruses. AT-527 was specifically designed as a purine nucleotide prodrug to inhibit viral RdRp and has shown *in vitro* activity in several assays against human coronaviruses, including SARS-CoV and SARS-CoV-2. We are currently evaluating AT-527 in a randomized, double blind, placebo-controlled Phase 2 trial in approximately 190 adult patients with moderate COVID-19 and one or more risk factors for poor outcomes. We dosed our first patient in September 2020 and expect to report topline data from this trial in the first half of 2021. We anticipate initiating a Phase 3 clinical trial to study AT-527 in adult patients with mild to moderate COVID-19 requiring outpatient management in the first half of 2021. In October 2020, we entered into the Roche License Agreement, granting Roche an exclusive license over the development and commercialization rights related to AT-527 outside of the United States (other than for certain hepatitis C virus uses). As part of the Roche License Agreement, we also granted Roche a license to manufacture AT-527 worldwide and agreed that Roche would manufacture the global commercial supply of AT-527. As part of the consideration, Roche agreed to pay us an upfront payment of \$350 million. See "Roche License Agreement."

[Table of Contents](#)

We are also developing additional small molecule antiviral product candidates for the treatment of HCV, dengue virus and RSV:

- For the treatment of chronic HCV infection, we have created a novel combination of AT-527 with AT-777, a nonstructural protein 5A, or NS5A, inhibitor into a single, oral, pan-genotypic fixed-dose combination product candidate, AT-787. Despite significant recent advances in treatment, HCV remains a global health burden due to the limitations of currently available treatment options. We believe that AT-787 has the potential to offer a short duration protease-sparing regimen for HCV-infected patients with or without cirrhosis. For patients with decompensated cirrhosis, a life-threatening stage of liver disease, AT-787 has the potential to treat these patients without the co-administration of ribavirin. Upon the resolution of industry wide clinical trial challenges associated with the COVID-19 pandemic, we expect to initiate our Phase 1/2A clinical trial, which is designed to evaluate the safety and pharmacokinetics, or PK, of different dosages of AT-777 in healthy adults and to evaluate the combination of AT-527 and AT-777 in HCV infected subjects.
- AT-752 is an oral, purine nucleotide prodrug for the treatment of dengue virus – a disease that infects up to 400 million people a year for which there are currently no therapies approved by either the U.S. Federal Food and Drug Administration, or the FDA, or European Medicines Agency, or EMA. AT-752 targets the inhibition of the dengue viral polymerase and, in preclinical studies, AT-752 showed potent *in vitro* activity against all serotypes tested as well as potent *in vivo* antiviral activity in a small animal model. We expect to initiate a randomized, double-blind, placebo-controlled Phase 1 trial to evaluate the safety and PK, of different dosages of AT-752 in healthy adults in the first half of 2021. Following the completion of the Phase 1 trial, we expect to initiate a Phase 2 trial to evaluate the antiviral activity, safety and PK of AT-752 in adult patients with dengue in the first half of 2021. Pursuant to the Roche License Agreement we retained rights to develop and manufacture AT-752 globally and to commercialize AT-752 in the United States for dengue, Japanese Encephalitis, West Nile virus, Yellow Fever and Zika. Rights to AT-752 for other indications were exclusively licensed to Roche. Roche agreed to negotiate in good faith an amendment to the Roche License Agreement pursuant to which Roche may commercialize AT-752 for dengue outside of the United States, unless Roche offers such commercialization right to us. Neither Roche nor we may commercialize AT-752 outside of the United States for dengue until we agree to an amendment to the Roche License Agreement. See “Roche License Agreement.”
- We are evaluating two lead compounds, AT-889 and AT-934, second-generation nucleoside pyrimidine prodrugs and other compounds for the treatment of RSV. AT-889 and AT-934 inhibit RNA polymerase through both initiation of viral replication and viral transcription and showed potent *in vitro* activity in several cell based assays against RSV. In the second half of 2021, we expect to file an IND or CTA and initiate clinical development of our selected product candidate.

Table of Contents

All of our product candidates have been discovered and developed internally and we retain full global rights to commercialize our product candidates, other than certain ex-U.S. rights licensed to Roche under the license agreement we entered into with Roche in October 2020, or the Roche License Agreement. We retain the right to commercialize all our product candidates in the United States. The following table summarizes our orally administered product candidate pipeline.

ssRNA virus	Indication	Product candidate	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
Coronaviridae	COVID-19 ¹	AT-527 ¹					Prior to end of 2020 <ul style="list-style-type: none"> Initiate virology/PK substudy Report Phase 2 interim safety data First half of 2021 <ul style="list-style-type: none"> Complete enrollment and report Phase 2 topline data Initiate Phase 3 outpatient trial Second half of 2021 <ul style="list-style-type: none"> Initiate Phase 3 post-exposure prophylaxis trial
Flaviviridae	Hepatitis C (HCV)	AT-787 ² (fixed-dose combo of AT-527 & 777)					First half of 2021 <ul style="list-style-type: none"> Initiate Phase 1 trial Second half of 2021 <ul style="list-style-type: none"> Initiate Phase 2 trial
		AT-527 (NS5B inhibitor)					
		AT-777 (NS5A inhibitor)					
Flaviviridae	Dengue ³	AT-752 ³					First half of 2021 <ul style="list-style-type: none"> Initiate and complete Phase 1 trial Initiate Phase 2 trial Second half of 2021 <ul style="list-style-type: none"> Report Phase 2 topline data
Paramyxoviridae	RSV	AT-889, AT-934 and other candidates					Second half of 2021 <ul style="list-style-type: none"> Initiate and complete Phase 1 trial Initiate Phase 2 trial

¹ In October 2020, we licensed to Roche the ex-U.S. development and commercialization rights related to AT-527 (other than for certain hepatitis C virus uses). See "Roche License Agreement."

² AT-787 is our selected product candidate for the treatment of HCV.

³ In October 2020, as a part of the Roche License Agreement we retained rights to develop and manufacture AT-752 globally and to commercialize AT-752 in the United States for dengue, Japanese Encephalitis, West Nile virus, Yellow Fever and Zika. We agreed with Roche that we would not commercialize AT-752 outside the United States unless we entered into a separate commercialization agreement with Roche to do so.

Our team

Our management team has significant experience discovering, developing and commercializing antiviral therapies for life-threatening viral infections. Our Founder, Chairman, and Chief Executive Officer, Jean-Pierre Sommadossi, Ph.D., has over 30 years of scientific, operational, strategic, and management experience in the biopharmaceutical industry, and holds more than 60 U.S. patents related to the treatment of infectious disease and cancer. Dr. Sommadossi was the principal founder of Idenix Pharmaceuticals, Inc., or Idenix, which was acquired by Merck & Co., Inc. in 2014, and a co-founder of Pharmasset, Inc., or Pharmasset, which was acquired by Gilead Sciences, Inc. in 2012.

We have assembled an experienced management and scientific team with a track record of success in the field of antiviral drug development, many of whom have worked together previously. Our team has significant expertise in nucleos(t)ide chemistry and biology and has applied that expertise towards the discovery and development of innovative antiviral treatments, including Epivir, Sovaldi, Tyzeka, Valtrex, Wellferon, Videx, Reyataz, Sustiva, Mavyret, Xofluza, Relenza and Zerit. Members of our team have held senior positions at AstraZeneca plc, GlaxoSmithKline plc, Chiron, Novartis International AG, Biogen, F. Hoffmann La Roche, Abbvie,

Bristol Myers Squibb, Shire, Biohaven Pharma, Pharmasset, Idenix, Valeant Pharmaceuticals International and Alnylam Pharmaceuticals.

We have been supported by a leading syndicate of investors, which include Adage, Aju IB Investment, Ally Bridge Group, Bain Capital Life Sciences, Cormorant Asset Management, Morningside Ventures, Omega Funds, Perceptive Advisors, PICTET, RA Capital, Redmile Group, RMI Partners, Rock Springs Capital, Sectoral Asset Management, T. Rowe Price and Valence Life Sciences.

Our strategy

Our goal is to become a global leader in the discovery, development, and commercialization of novel antiviral therapies for severe or life-threatening viral infections. We intend to achieve this goal by pursuing the following strategies:

- **Rapidly complete development and obtain approval for our lead product candidate, AT-527, an oral drug for the treatment of COVID-19.** We are currently evaluating AT-527 in a randomized, double-blind, placebo-controlled Phase 2 trial in approximately 190 adult patients with moderate COVID-19 and one or more risk factors for poor outcomes. We dosed the first patient in September 2020 and expect to report topline data from this trial in the first half of 2021. We intend to initiate a AT-527 Phase 3 trial enrolling patients with mild to moderate COVID-19 requiring outpatient management in the first half of 2021. We intend to work closely with the FDA and other regulatory authorities as we plan and implement our clinical trials to align on the most efficient regulatory pathway and may seek expedited development review programs such as Breakthrough Therapy designation.
- **Deploy our medicinal chemistry expertise and proprietary purine nucleotide platform against severe ssRNA viruses with high unmet need.** We are also developing additional small molecule antiviral product candidates for the treatment of HCV, dengue virus and RSV. We are developing AT-787, a co-formulated, oral, pan-genotypic fixed dose combination of AT-527 and AT-777, for the treatment of HCV. We believe AT-787 has the potential to shorten treatment duration compared to existing therapies, cure difficult-to-treat populations not currently served by existing therapies, and eliminate the need for ribavirin in patients suffering from decompensated cirrhosis. We are also developing AT-752 for the treatment of dengue virus, which we believe has the potential to be the first approved treatment for dengue fever – a disease that infects up to 400 million people each year. Finally, we are developing AT-889 and AT-934, second-generation nucleoside pyrimidine prodrugs, and other compounds for the treatment of RSV. We believe that the product candidate we develop could be the first therapy in over 30 years to be approved specifically for the treatment of RSV.
- **Focus on excellent clinical and regulatory execution.** We believe that building a successful antiviral-focused company requires very specific expertise in the areas of clinical study design and conduct and regulatory strategy. We have assembled a team with a successful track record of managing global clinical development activities in an efficient manner, and with multinational experience in obtaining regulatory approvals for antiviral therapeutics. Due to the high unmet need of the patients we seek to treat, we intend to work closely with the FDA and EMA to align on the most efficient regulatory pathways for our product candidates.
- **Maximize the value of our product candidates.** We generally intend to retain global commercialization rights to our product candidates, which we believe will allow us to retain the greatest potential value of our product portfolio. However, we may opportunistically enter into license agreements or collaborations where we believe there is an opportunity, particularly outside the United States, to maximize the value and accelerate the development of our product candidates and potential commercialization of any products. For example, in October 2020 we entered into the Roche License Agreement under which we granted an exclusive license for certain development and commercialization rights related to AT-527 outside of the United States to Roche. Currently, we plan to establish our own commercial organization in the United States and we may build additional organizations in other selected markets for any of our product candidates that are approved.

- **Maintain our entrepreneurial outlook, scientifically rigorous approach, and culture of tireless commitment to patients.** The patients we seek to treat suffer from life-threatening viral infections for which there are no approved therapies or the therapies that are approved have significant drawbacks which may include limited efficacy, or issues with safety and/or tolerability. Members of our team have dedicated their lives to discovering, developing, and commercializing novel antiviral therapies for severe or life-threatening viral infections. We intend to continue building our team of qualified individuals who share our commitment to collaboration and scientific rigor in the development of novel antiviral therapies that have the potential to treat or cure some of the world's most severe viral diseases.

Antiviral therapy

Background on viruses








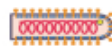






Viruses are cellular parasites that can only replicate using a host cell's replication processes, as viruses lack the machinery required to survive and replicate on their own. Unlike living organisms that use DNA as the basis for their genetic material, viruses can use either DNA or RNA. Approximately 70% of all viruses are RNA viruses.

Viruses have two primary components: nucleic acid (single or double stranded RNA or DNA) and a protective shell (the capsid). Some viruses may also have a lipid bilayer (the envelope) surrounding the capsid, an additional membrane derived from host cell membranes that contains viral proteins.

The viral replication process begins when a virus attaches itself to a specific receptor site on the host-cell membrane through attachment proteins. The replication mechanism is dependent upon whether the virus is an RNA or DNA virus. DNA viruses use host cell proteins and enzymes to make additional DNA that is used to copy the viral genome or is transcribed to messenger RNA, or mRNA. RNA viruses use their RNA as a template for synthesis of viral genomic RNA and mRNA. The mRNA then instructs the host cell to assemble viral structural proteins. Finally, the newly created virus particles, or virions, are released from the host cell in order to repeat the infection and replication cycle. RNA viruses can be particularly challenging to treat, as the error rates around the RdRp enzyme directed RNA synthesis cause high mutation rates during reproduction, creating resistance challenges for antiviral therapies.

Background of ssRNA viruses

RNA viruses can be ssRNA viruses or double-stranded, or dsRNA, viruses, depending on the type of RNA used as the genetic material. A virus encased within a lipid bilayer is known as an enveloped virus, while a virus without this bilayer is called a non-enveloped virus. Enveloped ssRNA viruses are the more prevalent cause of severe human viral diseases. Studies from the last decade have placed RNA viruses as primary etiological agents of many emerging human pathogens, representing as much as up to 50% of all emerging infectious diseases. Types of enveloped and non-enveloped ssRNA viruses and some of the diseases they cause are shown in the table below, with the types of ssRNA viruses that we are currently targeting with our product candidates highlighted in yellow.

Enveloped ssRNA viruses	
 <p>Coronaviridae - MERS - SARS - SARS-CoV-2</p>	 <p>Flaviviridae HCV, Dengue, West Nile, Zika, Yellow Fever, Japanese Encephalitis</p>
 <p>Paramyxoviridae - RSV - hMPV</p>	 <p>Retroviridae - HIV - Human T-Cell Leukemia Virus</p>
 <p>Bunyaviridae - La Cross encephalitis - Crimean-Congo hemorrhagic fever - Hantavirus pulmonary syndrome - Rift Valley fever</p>	 <p>Togaviridae - Alphavirus - EEE, Venezuelan equine encephalitis, chikungunya</p>
 <p>Orthomyxoviridae - H1N1 - Avian H7N9</p>	 <p>Rhabdoviridae - Rabies encephalitis</p>
 <p>Arenaviridae - Lymphocytic choriomeningitis virus (LCMV); - St. Louis Encephalitis, aseptic meningitis, Lassa Fever</p>	 <p>Filoviridae - Ebola - Marburg</p>
Non-enveloped ssRNA viruses	
 <p>Picornaviridae - Rhinovirus - Enterovirus</p>	 <p>Reoviridae - Rotavirus (GI disorders)</p>
 <p>Caliciviridae - Gastroenteritis</p>	 <p>Birnaviridae - Not a human pathogen</p>

Over the last 40 years, a great deal of progress has been made in the treatment of some of the most severe viral infections. However, many highly pathogenic ssRNA viruses, such as SARS-CoV-2 and dengue virus, remain untreated.

Viral polymerase as an antiviral target

From the discovery and approval of the first antiviral drug in 1963, there have been more than 100 antiviral drugs approved in the United States for the treatment of nine different human viral diseases. A historical challenge with the treatment of intracellular viruses has been selectivity or discovering drug targets that can completely inhibit viral replication without harming the host cells, leading to toxic side effects. Advances in technology and high throughput screening in recent years have driven the discovery of more selective antiviral product candidates. The viral polymerase, which is the single protein present in all RNA viruses, is a key enzyme in the replication of viruses, making for an ideal drug target as its core structural features are highly conserved across different viruses. There are four types of viral polymerase, depending upon the virus and its genomic makeup:

- RdRp: All ssRNA viruses, including SARS-CoV-2 and HCV, depend on the RdRp, encoded in the viral genome, for replication and transcription. Since these enzymes are not present in the host cell, this facilitates the design of selective inhibitors of viral replication, which target viral but not host cell polymerases.

[Table of Contents](#)

- DNA-dependent DNA polymerase, or DdDP: DdDP is used by DNA viruses to replicate their genome.
- RNA-dependent DNA polymerase, or reverse transcriptase: Reverse transcriptase is used by certain DNA or RNA viruses, such as HBV and HIV-1, to replicate their genomes.
- DNA-dependent RNA polymerase, or DdRP: DdRP is used by DNA viruses to transcribe mRNA from DNA templates during replication.

As RdRp-based synthesis does not occur in human host cells, antiviral drug development for RNA viruses focuses on identifying selective drug-like molecules that target viral RdRp. Advances in technology have enabled intensive structural and functional studies of viral polymerase and have opened avenues for the development of new and more effective antiviral therapies.

Viral resistance and mutations

A major obstacle to antiviral therapy is viral resistance. Resistance is a function of a virus' ability to genetically mutate, which, in the case of RNA viruses, is substantially higher than DNA viruses, as most RdRp lack proofreading abilities. The rate of mutation of RNA viruses can occur at six orders of magnitude greater than the rate of mutation of host cells. The ability of viruses to evolve makes the design of ssRNA-directed therapies challenging, as these viral strains continue to mutate and become more resistant to certain antiviral therapies over time. Since all the enzymes involved in the metabolic pathway of AT-511 to its active triphosphate are designed to be essentially ubiquitous host cell enzymes and not virally encoded proteins, we believe that the high rate of viral mutation does not affect the activation of the prodrug.

At times, combination therapy has been used to combat viral resistance for specific types of human viral infections. The guiding principles to decide when combination therapy may be needed, include: the in vitro inhibitory potency and human pharmacology of the antiviral; viral replication kinetics in patients; viral polymerase error rate; and whether the viral disease is an acute or a chronic infection. With RNA viruses, the treatment of acute infection, such as influenza is monotherapy (e.g., Tamiflu), as compared to the treatment of chronic infection, such as HCV, is combination therapy (e.g., Eplclusa). COVID-19, dengue and RSV are each the result of acute RNA viral infections.

Nucleos(t)ide analogs and prodrugs

Nucleic acid, which comprises human and viral genetic material, is composed of natural chemical compounds termed nucleosides and nucleotides. Nucleos(t)ide analogs are synthetic compounds that mimic naturally occurring nucleic acids, so that viral polymerases mistakenly incorporate these analogs as natural nucleic acids causing inhibition of viral replication. These synthetic nucleic acids, once modified into nucleosides and nucleotides within human cells, target the viral polymerase directly. Nucleos(t)ide analogs, compared to other classes of antiviral therapies have a high barrier to resistance due to the conservation of the nucleotide sequences in the RdRp that is required to produce viable virions.

Prodrugs of nucleos(t)ide analogs have become the backbone of therapies to treat life threatening viral infections, including HIV, HBV, and HCV. Prodrugs are employed to bypass rate limiting activation steps and, improve the oral bioavailability and permeation of cell membranes by the nucleos(t)ide analog.

Our platform

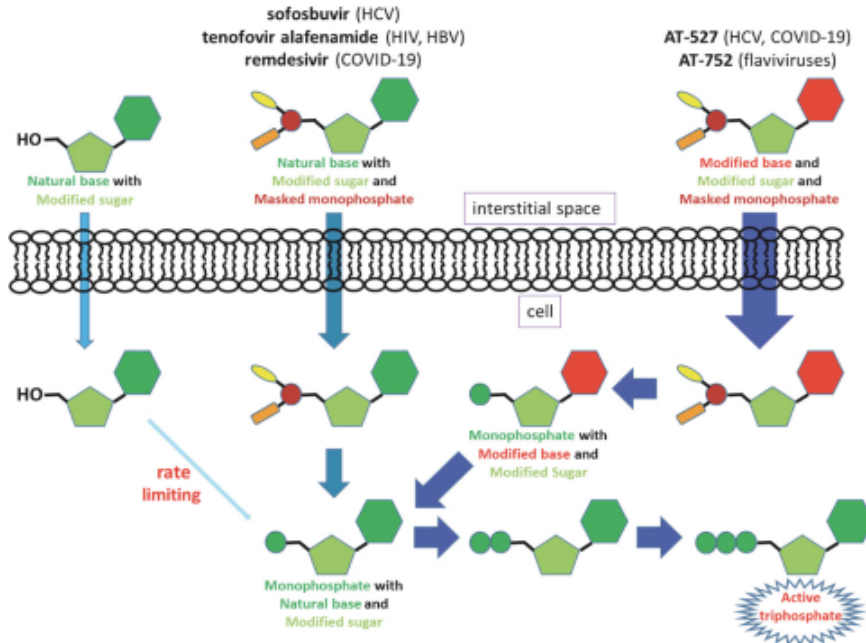
Leveraging our deep understanding of antiviral drug development, nucleoside biology, and medicinal chemistry, we have built a proprietary purine nucleotide prodrug platform to develop novel treatments for ssRNA viruses.

Table of Contents

Our proprietary nucleotide prodrug platform, as illustrated below, is comprised of the following critical components:

- specific modifications at the 6-position of the purine base, acting as a prodrug, enhance cell membrane permeability, resulting in an intermediate metabolite that maximizes formation of the triphosphate active metabolite in cells;
- stereospecific phosphoramidate, acting as a prodrug, designed to bypass the first rate-limiting phosphorylation enzyme in the intracellular activation pathway;
- specific modifications in the sugar moiety of the purine nucleotide scaffold, producing potent antiviral activity with a high degree of selectivity; and
- highly specific salt form to enhance solubility and drug bioavailability.

Atea's purine nucleotide prodrug platform



We believe that product candidates derived from our platform, which combines unique purine nucleotide scaffolds with a novel double prodrug strategy, have the following potential advantageous characteristics and features:

- enhanced antiviral activity and selectivity, as well as well-established pharmacology and animal models to predict clinical activity;
- favorable safety profile;
- convenience of once- or twice-daily oral administration; and
- efficient, predictable, scalable, and reproducible manufacturing, as well as long shelf life for potential stockpiling.

Our product candidates

Leveraging our proprietary purine nucleotide prodrug platform, we are advancing a pipeline of orally available, potent, and selective product candidates for difficult-to-treat, life threatening viral infections. All of our product candidates have been discovered and developed internally and we retain full global rights to commercialize our product candidates, other than certain ex-U.S. rights licensed to Roche under the license agreement we entered into with Roche in October 2020, or the Roche License Agreement. We retain the right to commercialize all our product candidates in the United States. The following table summarizes our product candidate pipeline.

ssRNA virus	Indication	Product candidate	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
Coronaviridae	COVID-19 ¹	AT-527 ²					Prior to end of 2020 <ul style="list-style-type: none"> Initiate virology/PK substudy Report Phase 2 interim safety data First half of 2021 <ul style="list-style-type: none"> Complete enrollment and report Phase 2 topline data Initiate Phase 3 outpatient trial Second half of 2021 <ul style="list-style-type: none"> Initiate Phase 3 post-exposure prophylaxis trial
Flaviviridae	Hepatitis C (HCV)	AT-787 ² (fixed-dose combo of AT-527 & 777)					First half of 2021 <ul style="list-style-type: none"> Initiate Phase 1 trial Second half of 2021 <ul style="list-style-type: none"> Initiate Phase 2 trial
		AT-527 (NS5B inhibitor)					
		AT-777 (NS5A inhibitor)					
Flaviviridae	Dengue ³	AT-752 ³					First half of 2021 <ul style="list-style-type: none"> Initiate and complete Phase 1 trial Initiate Phase 2 trial Second half of 2021 <ul style="list-style-type: none"> Report Phase 2 topline data
Paramyxoviridae	RSV	AT-889, AT-934 and other candidates					Second half of 2021 <ul style="list-style-type: none"> Initiate and complete Phase 1 trial Initiate Phase 2 trial

1 In October 2020, we licensed to Roche the ex-U.S. development and commercialization rights related to AT-527 (other than for certain hepatitis C virus uses). See "Roche License Agreement."

2 AT-787 is our selected product candidate for the treatment of HCV.

3 In October 2020, as a part of the Roche License Agreement we retained rights to develop and manufacture AT-752 globally and to commercialize AT-752 in the United States for dengue, Japanese Encephalitis, West Nile virus, Yellow Fever and Zika. We agreed with Roche that we would not commercialize AT-752 outside the United States unless we entered into a separate commercialization agreement with Roche to do so.

AT-527 for the treatment of COVID-19

SARS-CoV-2

Background

SARS-CoV-2 is a coronavirus, belonging to the *Coronaviridae* family, and is an enveloped virus with a positive sense ssRNA genome which encodes 29 viral proteins. It is one of six other human coronaviruses that exist, with four responsible for one third of common cold infections. To date, no therapies or vaccines have been developed that have proven effective for treating or preventing any of the six discovered coronavirus infections.

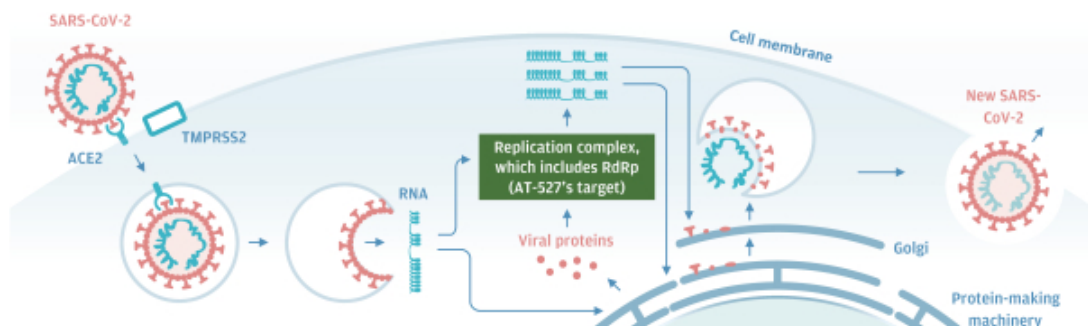
SARS-CoV-2 is structurally similar to two other life-threatening coronaviruses: SARS-CoV and Middle East Respiratory Syndrome coronavirus, or MERS-CoV-1. SARS-CoV-2 impairs respiratory function and spreads primarily from person to person via respiratory droplets among close contacts. Symptoms include fever, cough, shortness of breath and fatigue, with symptoms generally appearing two to 12 days after exposure. Severe complications include pneumonia, multi-organ failure, and death.

Table of Contents

SARS-CoV-2 was first identified as part of an investigation into an outbreak in Wuhan, China in December 2019, and is thought to have zoonotic origins. Case fatality rates, which measure the number of deaths as a percentage of total infections, have varied widely across different geographies due to variabilities in testing protocols and associated availability, differing demographics across different countries, differences in access to high quality healthcare, and variability in public policy responses for virus control. The World Health Organization, or WHO, estimated a case fatality rate of approximately 3% on March 3, 2020. The Centers for Disease Control, or CDC, has identified populations at high risk of severe illness, including the elderly, those residing in a long-term care facility, and those with underlying health conditions.

SARS-CoV-2 is a spherical virus that carries four different structural proteins: spike protein, envelope protein, membrane glycoprotein and nucleocapsid protein. As shown in the illustration below, the infection cycle begins when the spike proteins bind to the angiotensin-converting enzyme 2 cellular receptor, or ACE2, on the surface of the target cells. A second cell surface protein, transmembrane serine protease 2, or TMPRSS2, enables the virion to enter the cell, where it releases its RNA. Some of this RNA is translated into new proteins using the host cell's machinery—these proteins include the four structural proteins, as well as a number of non-structural proteins that form the replication complex. Within this complex, RdRps catalyze the synthesis of the approximately 30,000-nucleotide RNA viral genome. The proteins and RNA are then assembled into a new virion in the Golgi and released through exocytosis.

SARS-CoV-2 replication process



Given the lack of approved treatments or vaccines for SARS-CoV-2 infections, the primary approach employed to slow the potential transmission of the virus has been to confirm infections through diagnostic testing, followed by the isolation of any infected persons or communities. Testing access and capacity have varied greatly across different countries, as have standards required for testing. In the United States, CDC guidelines recommend analyzing a blend of both clinical and epidemiological evidence to determine potential exposure to SARS-CoV-2. If diagnostic testing is then warranted, the CDC recommends collecting and testing upper respiratory tract specimens via nasopharyngeal swab and, if available, the collection of lower respiratory tract specimens.

Based on data from 44,000 SARS-CoV-2 infected patients in China provided by the Chinese Centers for Disease Control and Prevention, researchers observed that approximately 81% of COVID-19 cases were mild to moderate, with an overall fatality rate of approximately 2%. Severe patients, or those with dyspnea, hypoxia, or greater than 50% lung involvement on imaging, represented approximately 14% of patients. A sub-group of approximately 5% of patients constituted the most critical cases, resulting in an approximately 50% fatality rate within this sub-group. In the United States, the CDC has estimated an overall cumulative hospitalization rate reported as of September 19, 2020 of approximately 174.8 per 100,000 people, with the highest rates in the elderly ages 65 years and older.

[Table of Contents](#)

Market opportunity

As of October 7, 2020, there were more than 35.6 million confirmed cases of COVID-19 worldwide, with more than 7.4 million cases and over 210,000 deaths from COVID-19 in the United States. This rate of mortality has COVID-19 on track to become one of the deadliest pandemics of the century.

Estimates for global peak cumulative infections vary, as epidemiologists have estimated an infection rate of between approximately 40% and 80% of the population. The lower end of this range would translate to total U.S. and global infections of 131 million and 3.1 billion, respectively.

The COVID-19 pandemic has caused a global public health and economic crisis. As a result, we believe governments are likely to stockpile an effective oral treatment for COVID-19. In response to the 2009 H1N1 swine flu pandemic, governments have been stockpiling Tamiflu, with stockpiles in the United States sufficient to treat 25% of the population, and those in France and the United Kingdom sufficient to treat 50% of the population. Due to the significant health and economic impact of COVID-19, we believe that future stockpiles of a safe and effective therapy could exceed those from the 2009 H1N1 swine flu. Given the novelty of COVID-19, the rapidly evolving response to its treatment, the possibility of the introduction of a vaccine, and the extent of subsequent waves, if any, of the pandemic, the market opportunity for a COVID-19 therapeutic is difficult to predict. However, we believe that stockpiling alone of a COVID-19 therapeutic presents a potentially multibillion-dollar market opportunity.

Treatment landscape

Several therapies and vaccines are currently being investigated to treat or prevent SARS-CoV-2 infection. These include small molecules designed to work as direct acting antivirals, which may be administered for both treatment and potentially prophylaxis, and antibody therapies that will require parenteral administration and may have application in both treatment and prevention. In addition to treatments directed at the virus, there are other immunomodulatory therapies such as interleukin-6 inhibitors, steroids, JAK inhibitors, and anti-tumor necrosis factor antibodies which are being developed to treat the host inflammatory response to the disease. Vaccines are being developed to prevent infection, and to create herd immunity, with the aim of preventing disease, and reducing the amount of virus circulating within the community. Antiviral therapies are complementary to vaccines, and we anticipate that antivirals will continue to be essential because of uncertainties around the level of immunity that the vaccines will be able to generate and the durability of such immunity.

Many therapies under investigation for treatment of COVID-19 were originally designed for other diseases, including HIV, Ebola, and malaria. Remdesivir, the prodrug of an adenosine nucleotide analog, developed for the treatment of ebola virus infection has shown *in vitro* activity against several coronaviruses, including SARS-CoV-2, and in interim data from an ongoing clinical trial, it has been shown that remdesivir accelerated recovery in patients with severe COVID-19. Based on these data and an increasing base of available scientific knowledge, the FDA has approved the use of remdesivir for the treatment of hospitalized adult and pediatric patients 12 years and older with suspected or laboratory-confirmed COVID-19, irrespective of the severity of disease and has granted remdesivir emergency use authorization for treatment of hospitalized pediatric patients under the age of 12 with suspected or laboratory-confirmed COVID-19. Remdesivir is, as of October 22, 2020 approved or authorized for temporary use as a COVID-19 treatment in approximately 50 countries worldwide. The bioavailability of remdesivir requires that it be administered via intravenous infusion, which we believe is likely to limit its use to hospitalized patients.

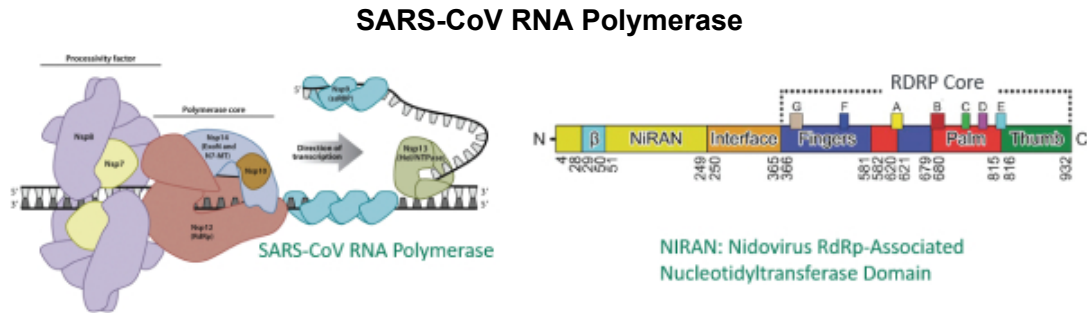
Other therapeutic agents under development for the treatment of COVID-19 that are RdRp inhibitors include favipiravir, a nucleoside analog approved in Japan for the treatment of emerging influenza strains and COVID-19, and EIDD-2801, a nucleoside analog that incorporates into the viral RNA leading to lethal accumulation of mistakes or "error catastrophe".

Table of Contents

An example of a monoclonal antibody in development is REGN-COV2, an antibody cocktail which targets two different areas of the receptor-binding domain on the spike protein of the coronavirus. Preliminary data from the first 275 outpatients enrolled in a Phase 1/2/3 study demonstrated reductions in viral load and time to symptom alleviation in seronegative patients. Antibodies are historically more complex than small molecules to manufacture and are administered parenterally. We believe that these two factors will impact and limit use of antibodies for treatment of patients with COVID-19.

Targeting RdRp to treat SARS-CoV-2

The RdRps in SARS-CoV and SARS-CoV-2 support the transcription and replication of their approximately 30,000-nucleotide RNA viral genomes. These RdRps are the largest and most complex RdRps among RNA viruses. As shown in the illustration below, the multi-subunit SARS-CoV RNA synthesis machinery is a complex of non-structural proteins, or nsps, that incorporates processivity factors (nsp-7, nsp-8), an RdRp core with a NIRAN domain (nsp-12), a proofreading exonuclease, a N7-methyl transferase (nsp-14), and a helicase (nsp-13), as well as predicted stimulatory cofactors and capping activities.



It is possible that any one or more than one of the non-structural proteins in the viral replication complex (RdRp) could be the target for inhibition of coronavirus replication, and the specific mechanism(s) of inhibition by the triphosphate formed from AT-511 is being investigated using SARS-CoV as the model virus. This potential mechanism includes incorporation of the triphosphate formed from AT-511 into the nascent RNA chain followed by premature termination of its elongation as has been observed with other nucleotide analog inhibitors and in other viruses. In addition, the active triphosphate metabolite may bind to the nucleotide binding site of the NIRAN function leading to its potent inhibition. Viral growth inhibition was demonstrated following impairment of the NIRAN function.

It is also conceivable that the proofreading exonuclease activity of nsp14 could remove the terminating analog nucleotide from the RdRp Core, and experiments are ongoing. However, the NIRAN function has no exonuclease activity.

Our approach

We are developing AT-527, an orally administered, novel antiviral product candidate, for the treatment of COVID-19 disease. In October 2020 we entered into a license agreement granting an exclusive license for development and commercialization rights outside of the United States related to AT-527 to Roche, including for the treatment of COVID-19 disease. We also granted Roche a license to manufacture AT-527 worldwide. AT-527 was specifically designed to uniquely inhibit viral RdRp. AT-511, the free base of AT-527, has shown *in vitro* antiviral activity against multiple ssRNA viruses, including human flaviviruses and coronaviruses.

Table of Contents

We assessed the *in vitro* potency of AT-511 against SARS-CoV and SARS-CoV-2. The data observed is summarized in the table below.

Antiviral activity was assessed after exposure of Huh-7 cells to virus and serial dilutions of test compound by determining the effective concentration required to reduce secretion of infectious virus into the culture medium by 90% (EC₉₀) after a 3-day incubation using a standard endpoint dilution CCID₅₀ assay to determine virus yield reduction (VYR). Half-maximal cytotoxicity (CC₅₀) was measured by neutral red staining of compound-treated duplicates in the absence of virus.

Since Huh-7 cells were unable to support infection by and replication of SARS-CoV-2, human airway epithelial (HAE) cell preparations were used to assess the activity of AT-511 against this virus, using the same method as described above. Cytotoxicity was assessed by visual inspection of the cells at the end of the 5-day incubation period.

In Vitro Activity of AT-511 (free base of AT-527) Against Human Coronaviruses

Virus (genus)	Cell line	Compound	Cytopathic Effect Assay CC ₅₀ (μM)	Virus Yield Reduction Assay EC ₉₀ (μM)	Selectivity Index (CC ₅₀ /EC ₉₀)
SARS-CoV (beta)	Huh-7	AT-511	>86	0.34	>250
SARS-CoV-2 (beta)	HAE	AT-511	>86 ^a / ^a >8.6 ^a / ^a >1.7 ^a	0.64/0.47/0.51	>130 />18/>3.3
		N ⁴ -hydroxycytidine	>19 ^a	3.9	>4.8
		remdesivir	>1.6	0.002	>800
		AT-034 (remdesivir)	>8.3/>1.6	0.27/0.014	>30/>110

^a Cytotoxicity assessed by visual inspection of cell monolayers

Huh-7, human hepatocyte carcinoma cell line (established ability to form triphosphate from AT-511) HAE, human airway epithelial cell culture (established ability to form triphosphate from AT-511)

N⁴-hydroxycytidine, nucleoside formed from EIDD-2801 (Ridgeback/Merck orally bioavailable ester prodrug)

AT-034 is commercial remdesivir (with COA) purchased by Atea and supplied blinded to be included in second assay

The EC₉₀ values for AT-511 against SARS-CoV and SARS-CoV-2 were 0.34 μM and an average of 0.5 μM from three independent experiments. The concentration of AT-511 required to exhibit CC₅₀ of the host cells used in these assays to support viral infection and propagation was consistently greater than the highest concentration tested (>86 μM). The sub-micromolar EC₉₀ values, in combination with the lack of toxicity observed in the host cells, suggests the potential for high potency and selectivity of AT-511 *in vitro* against these SARS coronaviruses.

The EC₉₀ for remdesivir, which was included in both SARS-CoV-2 assays as a positive control and also included as a blinded test article (AT-034) in the second assay, ranged from 0.001-0.27 μM. The potency of remdesivir, however, is likely a combination of its antiviral activity and cytotoxicity since dying and dead cells cannot support efficient viral replication. The CC₅₀ for remdesivir, determined by neutral red staining in the SARS-CoV assay conducted in human cells (Huh-7; less precise visual assessments without staining were used to determine cytotoxicity in the HAE assays) ranged from 5-11 μM. Similar *in vitro* cytotoxicity of remdesivir (1.7-36 μM CC₅₀) has been reported in other cell lines.

We also assessed the *in vitro* potency of N4-hydroxycytidine, the nucleoside formed from the oral prodrug EIDD-2801 currently being developed by Ridgeback/Merck for the treatment of COVID-19. N4-hydroxycytidine was eight times less potent than AT-511 in the same experiment. Lastly, sofosbuvir did not inhibit coronavirus replication at concentrations as high as 100 μM.

[Table of Contents](#)

In addition to assessing the *in vitro* potency of AT-511 against SARS-CoV-2 and SARS-CoV, we evaluated the formation and intracellular half-life of AT-9010, the active triphosphate metabolite of AT-527, in primary human nasal and bronchial epithelial cells. Also, we evaluated the pharmacokinetics and intracellular half-life of AT-9010 in tissues of non-human primates after oral administration of AT-527.

Substantial levels of the active triphosphate of AT-527 were formed in normal human bronchial and nasal epithelial cells incubated *in vitro* with 10 μM AT-511. After an 8-hour incubation, intracellular concentrations of the triphosphate were 698 and 236 μM in the bronchial and nasal cells, respectively. After replacement of the culture medium at 8 hours with fresh medium without AT-511, the half-life of the active triphosphate was determined to be 39 and 38 hours in the respective cell incubations. The accumulation and half-life of remdesivir triphosphate has been reported in the same type of human bronchial epithelial cells incubated with 1 μM remdesivir. After similar eight hour incubations, the concentration of remdesivir triphosphate, normalized to a dose of 10 μM , is at least 7-fold lower than the observed concentration of AT-9010 in the same cell type. In similar incubations of 1 μM remdesivir with human bronchial epithelial cells for two hours followed by washout of drug and continued incubation for 30 hours, the initial half-life of remdesivir triphosphate is less than 8 hours which is at least 4 times shorter than the half-life of AT-9010 in the same primary human lung cells suggesting the accumulation of higher levels of AT-9010 leading to a potentially greater antiviral effect after twice daily oral administration of 550 mg AT-527 versus daily intravenous administration of remdesivir (200 mg loading + 100 mg maintenance doses).

In non-human primates (NHP) administered AT-527 orally for three days in the form of a loading dose (60 mg/kg) followed by five doses (30 mg/kg each) 12 hours apart, intracellular concentrations of the active triphosphate metabolite in lung, kidney and liver tissue 12 hours after the last dose (trough levels with respect to twice daily dosing) were 0.14, 0.13 and 0.09 μM , respectively. Since the NHP doses were allometrically scaled to be equivalent to the initially intended clinical doses for COVID-19 subjects (1100 mg loading dose + 550 mg maintenance doses) and since *in vitro* levels of the triphosphate in primary NHP hepatocytes incubated with 10 μM AT-511 had previously been determined to be 7-fold lower than the corresponding levels in primary human hepatocytes, this ratio was used to predict steady-state intracellular trough triphosphate concentrations of 0.98, 0.91 and 0.62 μM in lung, kidney and liver tissues, respectively, of COVID-19 subjects treated with AT-527. The predicted trough concentration of the triphosphate in lung cells in prospective COVID-19 subjects was also obtained from a simulation of the steady-state plasma pharmacokinetics of AT-273 (surrogate for intracellular triphosphate concentrations) with twice daily dosing obtained from published data in HCV subjects given once-daily oral doses of 550 mg AT-527 and adjusted by the 1.6-fold greater triphosphate concentration in lung versus liver 12 hours after the last dose in NHP. This estimate is based on the established close pharmacokinetic-pharmacodynamic relationship between plasma AT-273 concentrations and the antiviral effect in HCV-infected patients. The predicted human lung trough concentration of the active triphosphate from this simulation (0.86 μM) was in good agreement with that obtained from the trough concentration scaled from NHP lung tissue (0.98 μM). We believe both predictions suggest that trough levels of the active triphosphate in COVID-19 patients during treatment with AT-527 should exceed the EC_{90} of 0.5 μM for AT-511 against SARS-CoV-2 replication. Moreover, we believe both predictions likely underestimate triphosphate trough levels in human lung since neither account for the extended intracellular half-life (39 hours) of the triphosphate in human lung epithelial cells.

Development history

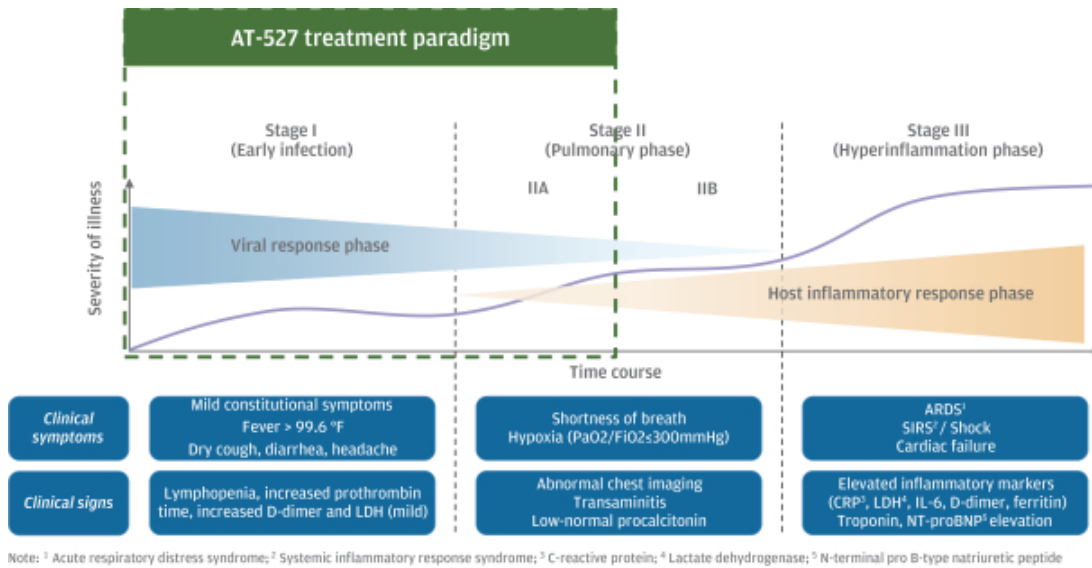
AT-527 was initially developed for the treatment of chronic HCV, and we have conducted two clinical trials of AT-527 in HCV. See *Hepatitis C virus (HCV)—Clinical development*. By utilizing data we obtained in our HCV clinical trials of AT-527, we were able to initiate our clinical development program of AT-527 for the treatment of patients with COVID-19 with a Phase 2 trial. Using the PK data from our HCV clinical trials, which showed

Table of Contents

50-60% bioavailability and a long intracellular half-life of the active triphosphate derived from AT-527, we have selected doses for our COVID-19 clinical trial that are intended to obtain drug exposure at pharmacologically relevant concentrations. The safety and tolerability of AT-527 has been evaluated in 82 clinical trial subjects comprised of 30 healthy volunteers (ages 29 to 65 years old) and 52 HCV-infected patients (ages 29 to 64 years old). No serious adverse effects were observed in these trials. The most common side effects observed were headache and small increases in blood lipid levels, with no consistent patterns in other reported side effects. Most side effects were not severe and were not thought to be related to AT-527.

Clinical development strategy

COVID-19 is an acute viral infection. We believe antiviral therapeutics should be most effective against COVID-19 within the first stage of the infection when the viral load is at its maximum, which is consistent with rapid viral replication initially in nasal cells, throat cells and ultimately pulmonary cells. As shown in the illustration below, we believe that the use of a potent, safe, oral antiviral therapeutic to treat SARS-CoV-2-infected individuals in the early stage of infection will mitigate the onset of severe COVID-19 and avert hospitalization.



Phase 2 clinical trial

We are currently conducting a randomized, double blind, placebo-controlled multi-center global Phase 2 trial of AT-527 which is expected to enroll approximately 190 COVID-19 hospitalized patients.

Patients eligible for enrollment in this Phase 2 clinical trial are aged 45 to 80 years with moderate COVID-19 illness and at least one risk factor suggestive of poor outcome (such as obesity, hypertension, a history of diabetes, or a history of asthma). Moderate severity is defined as having at least one symptom of lower respiratory infection consistent with COVID-19, as well as oxygen saturation below 93% on room air or requiring £2L/min oxygen to maintain oxygen saturation in excess of 93%. The primary efficacy endpoint is the change in level of respiratory insufficiency, assessed on an ordinal 6-category scale of respiratory support levels, as compared to placebo, where a statistically significant finding would be reflected by a significantly lower probability for AT-527-treated subjects to exhibit a worsening of respiratory insufficiency (requiring £2

[Table of Contents](#)

level higher respiratory support) during the study compared to placebo recipients. The six categories of the ordinal scale are: (1) no respiratory support; (2) low-level passive O₂ supplementation (up to 2 L/min) by mask or nasal cannula; (3) higher O₂ supplementation (>2 L/min); (4) any non-invasive form of positive-pressure oxygenation/ventilation; (5) invasive respiratory support; and (6) death. We believe the most important outcomes to be assessed in this trial are the reduction in progression to higher levels of required respiratory support, which we believe could be life-saving for patients with significant risk factors, as well as reduced duration of the COVID-19 acute illness and hospitalizations.

Trial participants are being randomized 1:1 (AT-527: placebo). The first 20 patients (10 AT-527, 10 placebo) received a dose of either 550 mg free base of AT-527 or placebo twice daily for five days in addition to supportive standard of care. In accordance with the protocol, an independent Data Safety Monitoring Board, or DSMB, conducted a safety review and approved continued enrollment of patients in the trial.

In accordance with the protocol, we are enrolling a second cohort of 20 patients and enrollment will again be paused for a planned DSMB review of the safety data associated with this second cohort of 20 patients. Upon DSMB approval to proceed after the second cohort of 20 patients, the enrollment of the remainder of the patients will be re-initiated with planned pauses and DSMB reviews at each of the 50% and 75% enrollment levels.

To enhance the virological data we may derive from the Phase 2 clinical trial, we are planning to add a virology pharmacokinetic/pharmacodynamic sub-study which will be conducted at a limited number of the clinical trial sites participating in the Phase 2 clinical trial. This sub-study will include additional biological sampling for quantitative (viral load) evaluation.

We expect to complete enrollment and report topline data from the Phase 2 trial and virological sub-study in first half of 2021.

Planned clinical development

In addition to the Phase 2 clinical trial, we also plan to conduct a Phase 1 clinical trial of AT-527 in up to 20 healthy volunteers. From this clinical trial, we anticipate obtaining additional pharmacokinetics and safety data of AT-527 at the 550 mg twice daily dose. We expect to initiate and complete enrollment in the healthy volunteer clinical trial prior to the end of 2020.

After receiving the safety results from at least 40 patients enrolled in our Phase 2 trial as well as the supportive data from the healthy volunteer clinical trial, we expect to initiate a Phase 3 clinical trial to study AT-527 in patients with mild to moderate COVID-19 requiring outpatient management.

We are designing this Phase 3 trial to enroll up to 600 patients aged 18 years or older. The primary objective of the trial is expected to be evaluation of the efficacy of AT-527 compared to placebo by measuring the time to alleviation of symptoms, or TAS, in patients with SARS-CoV-2 virus infection with mild or moderate disease. The primary endpoint of TAS is defined as the time when all COVID-19 symptoms are assessed and self reported by the patient as none or mild for a duration of at least 24 hours. Patients will assess the severity of disease on a 4-point scale (with 0 indicating no symptoms, 1 mild symptoms, 2 moderate symptoms, and 3 severe symptoms).

We are also planning to conduct a randomized double-blind, post-exposure prophylaxis Phase 3 clinical trial evaluating the reduction of direct transmission from SARS-CoV-2 infected patients (index case) to contacts. We expect to enroll approximately 2,000 patients aged 18 years or older. Pending additional discussions with regulatory authorities, the primary endpoint is expected to be the proportion of participants who test positive by PCR at predetermined timepoints.

[Table of Contents](#)

To align on the most efficient regulatory pathway for AT-527 in COVID-19, we intend to work closely with the FDA and other regulatory authorities as we plan and implement the clinical trials described above. We may pursue expedited FDA review and approval programs, such as Breakthrough Therapy designation.

We are currently conducting manufacturing campaigns at third-party contract manufacturers that is expected to result, when combined with our current drug tablet inventory, in an inventory of AT-527 275 mg and 550 mg tablets and matching placebo that is expected to satisfy the clinical trial material requirements for our currently planned COVID-19 clinical trials. Additionally, we, together with Roche, are engaged, through our contract manufacturers, in the optimization of the synthetic process and formulation for commercial scale manufacture of AT-527 275 mg and 550 mg tablets. We are targeting availability of initial commercial supply of AT-527 beginning in 2021.

AT-787 for the treatment of hepatitis C

Hepatitis C virus (HCV)

Background

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. Injection drug use accounts for approximately 60% of all new cases of HCV. Diagnosis of HCV is made through blood tests, including molecular tests that allow for the detection, quantification and analysis of viral genomes and the classification of an infection into specific viral genotypes. Hepatitis C becomes chronic Hepatitis C in 75% to 85% of cases, with an incubation period lasting from two to 26 weeks.

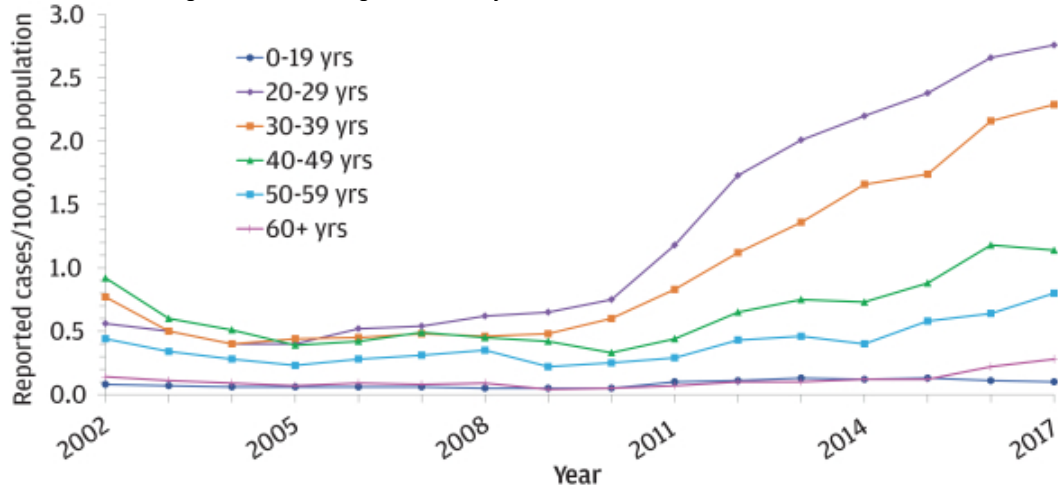
HCV is classified into seven genotypes and 67 subtypes, with genotype 1 responsible for more than 70% of HCV cases in the United States. Patients with HCV are also classified by liver function status: compensated cirrhosis (liver scarring) denotes those patients that do not yet have impaired liver function, while decompensated cirrhosis describes patients with moderate to severe liver function impairment.

Market opportunity

According to the WHO, an estimated 71 million people are chronically infected with HCV, a significant portion of which are likely to develop cirrhosis or liver cancer. Of those infected with HCV, only 20% are diagnosed and 2% are treated globally. The WHO estimates that 399,000 people died from HCV in 2016.

[Table of Contents](#)

As shown in the table below, the CDC reported that new infections in the United States have increased substantially from 2011 to 2017 with the greatest increase in incidence occurring in individuals ages 20 to 39 years old.



Despite recent advances in treatment, there remains a large undeserved HCV patient population which continues to grow. The CDC estimated the incidence of HCV in 2018 increased by 50,300 cases in the United States. In 2019, aggregated global sales of direct acting antiviral HCV therapeutics manufactured by Gilead Sciences, Inc. and AbbVie Inc. approximated \$5.8 billion. It is estimated that a substantial global market for HCV therapeutics will exist to 2050 and beyond.

Current treatment landscape

No vaccine exists for the prevention of HCV, but several recently introduced oral antiviral therapeutics have boosted sustained virologic response rates to over 95% in a majority of patients, with treatment durations reduced to eight to 12 weeks depending upon the regimen and patient population. There are three classes of direct acting antiviral therapeutics, defined by their mechanism of action and therapeutic target: NS3/4A protease inhibitors, NS5A inhibitors, and NS5B non-nucleos(t)ide polymerase inhibitors. A patient's genotype, cirrhotic status, and prior treatment failures determine the appropriate antiviral therapeutic used in treatment. The two leading therapeutics for treatment of chronic HCV are:

- **Epclusa** (sofosbuvir/velpatasvir): Epclusa was first approved by the FDA in 2016 for the treatment of adults with chronic HCV infection with any of genotypes one through six infection, either without cirrhosis or with compensated cirrhosis. For patients with decompensated cirrhosis, Epclusa is approved for use in combination with ribavirin. Patients on Epclusa require 12 weeks of treatment.
- **Mavyret** (glecaprevir/pibrentasvir): Mavyret was first approved by the FDA in 2017 for the treatment of adults with chronic HCV with any of genotypes one through six infection, without cirrhosis or with compensated cirrhosis. Mavyret is also approved for HCV patients with genotype 1 infection who have been previously treated with a regimen either containing an NS5A inhibitor or an NS3/4A protease inhibitor (but not both). Mavyret was the first eight-week treatment approved for HCV genotypes one through six in adult patients without cirrhosis who have not been previously treated. In 2019, the FDA approved shortening the

[Table of Contents](#)

treatment duration from 12 weeks to eight weeks in treatment-naïve, compensated cirrhotic HCV patients across all genotypes one through six. Mavyret is not approved for use in patients with decompensated cirrhosis.

Our approach

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. Based on our preclinical and clinical data to date, we believe that AT-787, if approved, could offer the following potential benefits over currently available treatments:

- Shorten treatment duration to eight weeks in non-cirrhotic and compensated cirrhosis HCV in all genotypes. Current HCV therapies typically require longer dosing in cirrhotic patients to achieve a sustained virologic response, or SVR, that is close to, but often proportionally lower, than the SVR achieved with shorter treatment of non-cirrhotic patients.
- Equivalent antiviral potency across all genotypes, regardless of cirrhotic status, including the difficult to treat genotype-3 population.
- Obviate the need for extensive pretreatment assessments required by current treatment options, including genotyping, fibroscan (if cirrhosis is present), and liver function assessment.
- Eliminate the need for ribavirin in patients with decompensated cirrhosis. Ribavirin, an antiviral first approved in 1986, carries several FDA “black box” warnings, including the risk of hemolytic anemia and teratogenicity.
- Well tolerated, with low potential for drug-drug interactions. Mavyret, which carries an FDA warning for cirrhotic patient treatment, is not to be prescribed for patients on atazanavir or rifampin, while Epclusa could cause a slow heart rate when taken with amiodarone.

Clinical development

We have conducted two clinical trials of AT-527.

Phase 1 clinical trial of AT-527

We conducted a Phase 1 trial to evaluate single and multiple doses of AT-527 as a single agent in healthy and HCV-infected subjects for up to seven days. All HCV-infected subjects were treatment-naïve with HCV RNA $\geq 5 \log_{10}$ IU/mL. The objectives of the trial were to assess safety, tolerability, PK and antiviral activity.

The trial evaluated single oral doses of AT-527 up to 369 mg free base (400 mg salt form) in healthy subjects (Part A), single doses up to 600 mg salt form (553 mg free base) in non-cirrhotic HCV-infected subjects (Part B), and multiple doses up to 600 mg salt form (553 mg free base) once daily for seven days in non-cirrhotic genotype 1b, or GT1, HCV-infected subjects (Part C). Additional cohorts evaluated 600 mg salt form (553 mg free base) once daily for seven days in non-cirrhotic genotype 3, or GT3, (Part D) and Child-Pugh A cirrhotic genotype 1b/3, or GT1b/2, HCV-infected subjects (Part E). The tables below show the dosage and mean maximum HCV RNA reductions for each treatment cohort.

A total of 88 subjects were dosed across all parts of the trial, with 72 subjects who received active drug and 16 subjects who received placebo. In this trial, AT-527 showed equivalent pan-genotypic antiviral activity in both cirrhotic and non-cirrhotic HCV infected patients. The mean HCV reduction within 24 hours after a single dose was up to 2.4 \log_{10} IU/mL, and the mean maximum HCV RNA reduction after seven days of dosing with AT-527 at

[Table of Contents](#)

553 mg free base was 4.6 log₁₀ IU/mL. Data also showed a mean maximum HCV RNA reduction of 4.4 log₁₀ IU/mL after seven days of dosing of AT-527 at 553 mg free base in non-cirrhotic genotype 1b, or GT1b, HCV-infected subjects, and a mean reduction of 4.5 log₁₀ IU/mL after seven days of dosing in non-cirrhotic GT3 HCV-infected subjects. The PK data in cirrhotic subjects was similar to non-cirrhotic subjects. E_{max} modeling predicted that a dose of 553 mg free base of AT-527 once daily would result in maximum viral load reduction.

TABLE 3

Maximum HCV RNA change in Part B (single dose in non-cirrhotic, GT1 HCV-infected subjects)

Maximum Reduction (log ₁₀ IU/mL) AT-527 dosage (free base equivalent)	100 mg (92 mg) N=3	300 mg (277 mg) N=3	400 mg (369 mg) N=3	600 mg (553 mg) N=3
Mean±SD*	0.8 ±0.153	1.7 ±0.564	2.2 ±0.391	2.3 ±0.255
Individual	0.6, 0.8, 0.9	1.1, 1.8, 2.2	1.8, 2.2, 2.5	2.1, 2.3, 2.6

Maximum HCV RNA change in Part C (multiple dose in non-cirrhotic, GT1 HCV-infected subjects)

Maximum Reduction (log ₁₀ IU/mL)	Placebo QD** x 7 days (N=6)	150 mg (138 mg) QD x 7 days (N=6)	300 mg (277 mg) QD x 7 days (N=6)	600 mg (553 mg) QD x 7 days (N=6)
Mean ±SD	0.4±0.109	2.6±1.073	4.0±0.415	4.4±0.712
Individual	0.3, 0.3, 0.4, 0.4, 0.5, 0.6	1.7, 1.8, 1.8, 2.7, 3.0, 4.5	3.4, 3.7, 3.9, 4.2, 4.2, 4.5	3.5, 4.0, 4.1, 4.3, 5.2, 5.3

Maximum HCV RNA change in Part D (multiple dose in non-cirrhotic, GT3 HCV-infected subjects) and Part E (multiple dose in cirrhotic HCV-infected subjects)

Maximum Reduction (log ₁₀ IU/mL)	Part D – GT3 600 mg (553 mg) QD x 7 days (N=6)	Part E – Cirrhotic 600 mg (553 mg) QD x 7 days (N=6)
Mean ±SD	4.5±0.262	4.6±0.485
Individual	4.2, 4.4, 4.4, 4.5, 4.5, 5.0	GT1b: 4.0, 4.0, 4.5 GT2: 5.0 GT3: 4.8, 5.2

* SD = standard deviation

** QD = twice daily

Phase 2 clinical trial of AT-527 in combination with an NS5A inhibitor

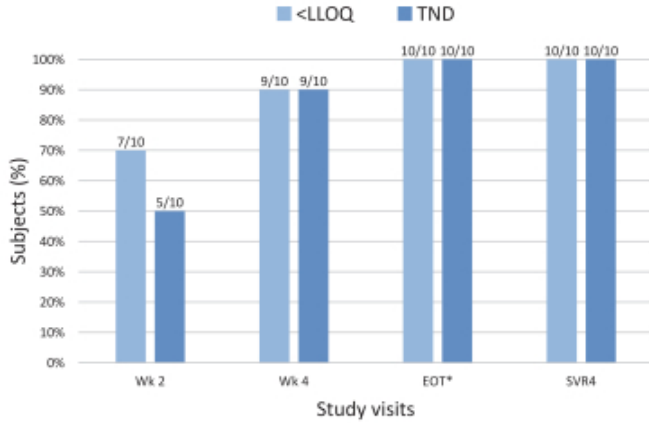
We conducted a Phase 2, open-label clinical trial to evaluate AT-527 in combination with daclatasvir, an approved commercially available HCV NS5A inhibitor, in HCV-infected subjects. Ten treatment-naïve, non-cirrhotic GT1 HCV-infected subjects received 553 mg free base AT-527 and 60 mg daclatasvir once daily for a period of eight or 12 weeks. The primary efficacy endpoint of the study was an SVR of 12, with secondary efficacy endpoints that included HCV RNA < Lower Limit Of Quantitation, or LLOQ, and Target Not Detected, or TND, by study visit, HCV RNA changes from baseline, alanine transaminase normalization in those who had

Table of Contents

elevated levels at baseline, virologic failure, and resistance-associated substitutions to either of the study drugs. All subjects completed the treatment period in the study, nine of whom received eight weeks of treatment and one of whom received 12 weeks of treatment. All subjects achieved an SVR of four, nine of whom received only eight weeks of treatment. As shown in the graph below, viral load decreased rapidly, with 70% of subjects achieving plasma HCV RNA < LLOQ by week 2 (and 50% achieving TND by week 2). We believe that the rapid early clearance of HCV RNA observed in this trial supports continued evaluation of AT-527 in shortened treatment regimens, ideally with a more potent, next-generation HCV NS5A inhibitor.

FIGURE 10

Proportion (%) of subjects who achieved HCV RNA <LLOQ and TND by study visit with AT-527 in combination with daclatasvir



LLOQ: lower limit of quantification; TND: target not detected

*End of treatment (EOT) = 8 wks for 9 subjects and 12 wks for 1 subject

AT-527 Safety Results

There were no serious adverse events, dose-limiting toxicities or adverse events leading to trial discontinuation observed in our Phase 1 or our Phase 2 clinical trial of AT-527. The most common side effects observed were headache and small increases in blood lipid levels, with no consistent patterns in other reported effect. Most side effects were not severe and were not thought to be related to AT-527.

Planned clinical development

We have temporarily paused our development program for AT-787 in HCV infected patients, given industry-wide challenges in clinical studies during the COVID-19 pandemic. We expect to restart this program once the planned clinical trial sites are able to re-open and we elect to resume patient enrollment, 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. We currently anticipate that this will occur in the first half of 2021. The Phase 1/2A clinical trial is comprised of two parts. Part A is a randomized, blinded, sequential-dose trial to evaluate the safety, tolerability and PK of AT-777 alone in up to 24 healthy volunteers. Part B is an open-label trial in up to 20 patients with HCV to evaluate AT-527 in combination with AT-777. The primary objective of Part B are safety, antiviral activity and PK. Following the completion of the Phase 1/2A clinical, we anticipate commencing a Phase 2b clinical trial to further evaluate the antiviral activity and safety of AT-787, the fixed dose combination of AT-777 and AT-527.

AT-752 for the treatment of dengue

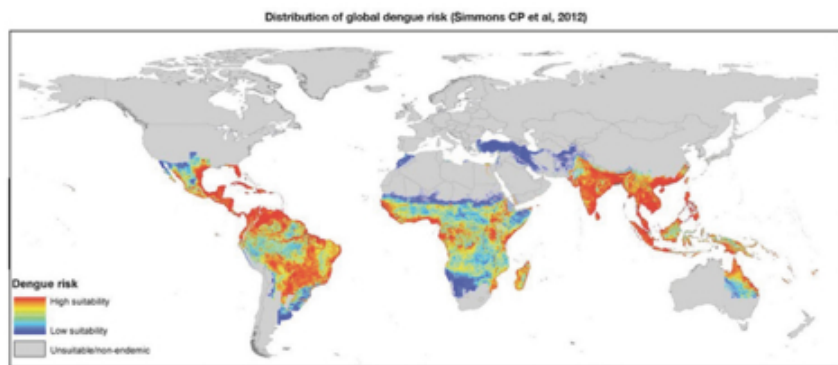
Dengue virus

Background

Dengue, which is caused by a positive sense ssRNA virus belonging to the *Flaviviridae* family, is a mosquito-borne viral infection. Dengue causes flu-like symptoms in both children and adults and is spread through the bite of an infected mosquito. There are five dengue viral serotypes, and infection with serotype does not produce immunity to another serotype. Thus, a person could be infected with dengue multiple times and reinfection typically results in a more severe disease. Symptoms include fever, eye pain, headache, swollen glands, rash, muscle pain, bone pain, nausea, vomiting, and joint pain, and last two to seven days post-infection.

Market opportunity

Globally, three billion people, or roughly 40% percent of the world's population, live in high-risk dengue areas, while up to 400 million are infected each year, resulting in 500,000 hospitalizations. The WHO has called dengue the most important mosquito-borne viral disease in the world. Although dengue rarely occurs in the continental United States, it is endemic in Puerto Rico, Southeast Asia, Latin America and the Pacific Islands, as shown in the map below. Seventy percent of the global disease burden for dengue is in Asia.



According to the CDC, 5% of infected patients develop a life-threatening form of dengue called severe dengue. Those who develop severe dengue may have some or all of the following complications: severe abdominal pain, fatigue, severe bleeding, organ impairment, and plasma leakage. The mortality rate of severe dengue ranges between 12% and 44%, if left untreated. The global economic cost burden of dengue was estimated at \$8.9 billion in 2013, with nearly 50% of the costs associated with hospitalizations. We estimate the commercial market for a treatment of dengue to be approximately \$500 million.

Current treatment landscape

There are no FDA or EMA approved therapies indicated for the treatment of dengue. Current treatment protocols involve supportive care, including analgesics, judicious fluid replacement, and bed rest. In 2019, a vaccine, Dengvaxia developed by Sanofi Pasteur Inc., or Sanofi, was approved by the FDA for the prevention of disease caused by dengue virus serotypes 1, 2, 3 and 4 in children ages nine to 16 with laboratory-confirmed previous dengue infection and living in endemic areas.

Takeda Pharmaceuticals Co Ltd, or Takeda, is also advancing a dengue vaccine, TAK-003, which is in Phase 3 development. Primary endpoint analysis of its ongoing Phase 3 trial in children ages four to 16 years showed protection against virologically-confirmed dengue.

[Table of Contents](#)

Our approach

We are developing AT-752, an oral, purine nucleoside prodrug product candidate. AT-752 has shown potent activity against all serotypes tested in preclinical studies. AT-752 works by targeting the inhibition of the dengue viral polymerase. We intend to explore the potential development of AT-752 as a prophylactic treatment for dengue, which if approved, could be directed at the travelers' market. In October 2020, as a part of the Roche License Agreement, we agreed that we would not commercialize AT-752 outside the United States unless we entered into a separate commercialization agreement with Roche to do so.

Preclinical development

We have conducted preclinical studies of AT-752 in which we pre-treated AG129 mice with AT-752 (1000 mg/kg, p.o.) for four hours before subcutaneous inoculation with D2Y98P dengue strain and subsequent dosing of AT-752 twice daily (500 mg/kg, p.o.) for seven days, starting one hour post inoculation. This disease model, which ultimately resulted in fatal central nervous system sequelae, showed notable differences in overall health, survival, and viremia between AT-752-treated mice and mice that were treated with vehicle. As shown in the graphs below, viral RNA in serum was statistically significantly lower than control by day 6 and below the limit of detection, or LOD (LOD: 50 copies per mL) on day 8, after seven days of drug treatment.

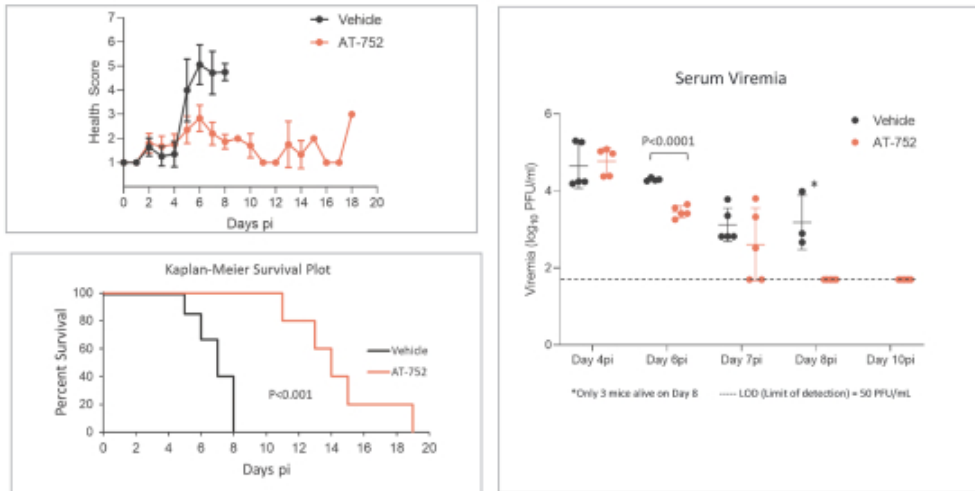


Table of Contents

The antiviral activity of AT-281, the free base of AT-752, was evaluated under contract with the National Institutes of Health and Infectious Disease against a variety of flaviviruses. Huh-7 cells were infected with individual viral strains and exposed to serial dilutions of AT-281. A virally induced cytopathic effect, or CPE, assay using a neutral red dye uptake endpoint or a virus yield reduction measurement using a standard endpoint dilution CCID₅₀ assay was used to measure the antiviral EC₅₀ or EC₉₀ value, respectively. Uninfected cell controls concurrently exposed to drug were used to determine cytotoxicity (CC₅₀) using the CPE assay. AT-281 demonstrated sub-micromolar potencies against all flaviviruses tested (summarized in the table below), with an EC₉₀ of 0.64 µM against Dengue type 2 and an EC₅₀ of 0.77 µM against Dengue type 3. No toxicity was detected for AT-281 up to the highest concentration tested (172 µM).

Virus	Strain	EC ₉₀ (µM)	CC ₅₀ (µM)	SI ^a
Dengue type 2	New Guinea C	0.64	>172	>270
Dengue type 3	H87	0.77 ^b	>172	>220
Japanese encephalitis	SA-14	0.21 ^a	>172	>820
West Nile	Kern 515, WNo2	0.43	>172	>400
Yellow Fever	YFV 17D	0.26	>172	>660
Zika	MR766	0.64 ^a	>172	>270

^a Selectivity index (CC₅₀/EC₉₀ or CC₅₀/EC₅₀)

^b EC₅₀

Planned clinical development

We plan to submit an IND to the FDA or Clinical Trial Application to one or more competent authorities in countries outside the United States prior to the end of 2020. Contingent upon receipt of FDA or other competent authority authorization, we expect to initiate a randomized, double-blind, placebo-controlled Phase 1 trial to analyze the safety and PK of several different dosages of AT-752 in 50 to 60 healthy adult subjects in the first half of 2021. Following the completion of the Phase 1 trial, we expect to initiate in the first half of 2021 a Phase 2 trial of AT-752 in 60 to 80 adult subjects with dengue, to evaluate antiviral activity, safety and PK. The trial may be conducted in Asia. We expect that the trial's endpoints will include reductions in viral load, fever and time to clearance of non-structural protein 1. We intend to pursue FDA expedited development and review programs for AT-752. Dengue is also defined as a tropical disease under the Federal Food, Drug and Cosmetic Act, or FDCA, and therefore FDA approval of AT-752 for the treatment of Dengue may result in a priority review voucher.

AT-889, AT-934 and other candidates for the treatment of respiratory syncytial virus (RSV)

Respiratory syncytial virus

Background

RSV is a seasonal respiratory virus that can be serious for infants, older adults, and the immuno-compromised population. Although the virus is seasonal, the duration, peaks and severity of the virus vary each season. RSV, a negative ssRNA virus belonging to the *Pneumoviridae* subfamily of the *Paramyxoviridae* family, is the most

[Table of Contents](#)

common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs) in children in the United States. Almost all children contract the RSV infection by their second birthday.

The primary symptoms of RSV infections include coughing, wheezing, fever, decreased appetite, and runny nose. In the United States, RSV infections generally occur during fall, winter and spring, but the timing and severity can vary from year to year and from region to region. Two different strains of the virus co-circulate each season, and RSV epidemics last from four to six months.

Market opportunity

Globally, RSV affects 64 million people, according to the National Institutes of Health, or the NIH, with annual mortality estimated at 160,000 deaths. The market for RSV treatment is estimated to exceed \$5 billion by 2024.

We expect to target three distinct populations over time with our product candidates: the elderly, the immunocompromised and children, with an initial focus on the elderly.

- **Elderly:** Among the elderly, the CDC estimates that RSV is responsible for 177,000 hospitalizations in the United States. An estimated 14,000 annual deaths are caused by RSV in the United States in adults older than age 65.
- **Immunocompromised:** Globally, there are more than 50,000 hematopoietic stem cell transplants annually. Studies suggest that there is a significant risk of hospital mortality due to respiratory failure in immunocompromised patients with lower respiratory disease.
- **Children:** The NIH estimates that RSV results in 75,000 to 125,000 child hospitalizations in the United States. Globally, it is estimated that RSV results in 3.2 million hospital admissions in children younger than five years of age.

Current treatment landscape

Treatment for RSV typically focuses on supportive care, which can include nasal suction, fever management, hydration, and oxygen. The FDA approved aerosolized ribavirin in 1986 for the treatment of serious RSV infections in hospitalized children. However, ribavirin, a nucleoside analog, carries a number of safety concerns, including potential toxicity for exposed persons. Aerosolized ribavirin has not been approved for use in the elderly or immunocompromised populations.

In addition, the FDA approved Synagis (palivizumab) in 1998 for the prevention of lower respiratory tract disease caused by RSV in children at high risk of RSV disease. Synagis is administered as an injection every month during RSV season. Synagis has not been approved for treatment of RSV, nor is it indicated for use in populations other than children under 24 months of age.

Our approach

We are evaluating two lead compounds, AT-889 and AT-934, second-generation nucleoside pyrimidine prodrugs, and other compounds. Our development efforts in RSV have focused on two strategies: fusion inhibitors and replication inhibitors (both nucleoside and non-nucleoside). We believe AT-889, AT-934 or one of our other product candidates for RSV has the potential to inhibit both the initiation of viral replication, as well as viral transcription. We plan to develop our product candidate in both oral and parenteral dosage formulations.

[Table of Contents](#)

Development history

We have observed the antiviral potency and selectivity of AT-889 and AT-934 against RSV in *in vitro* cell-based assays. The EC₅₀ to inhibit replication of the RSV (strain A Long) was 0.20 μM for AT-889 and 0.46 μM for AT-934. The concentrations of both compounds required to exhibit a CC₅₀ of the host cells used in these assays were greater than 50 μM.

Development strategy

Currently, we are evaluating the antiviral activity of AT-889 and AT-934 and other compounds in *in vitro* studies to inform our selection of a lead candidate. Once chosen, we will assess the *in vivo* antiviral activity of such lead candidate in a small animal model, and conduct IND-enabling toxicology studies. Thereafter we intend to nominate a product candidate for clinical development. We anticipate nominating our product candidate and initiating a Phase 1 trial to evaluate safety and PK of this product candidate in healthy subjects in the second half of 2021. Following completion of the Phase 1 trial, we expect to initiate a Phase 2 trial in adult subjects with RSV to evaluate antiviral activity, safety and PK in the second half of 2021.

Roche License Agreement

In October 2020, we entered into a license agreement, or the Roche License Agreement, with F. Hoffmann-La Roche Ltd and Genentech, Inc. in connection with AT-511, AT-527, their backup compounds (including AT-752), or the Compounds, products containing any Compound, or the Products, and related companion diagnostics, or the Companion Diagnostics.

Subject to the terms and conditions of the Roche License Agreement, we granted Roche (i) an exclusive, sublicensable, worldwide (excluding the United States) license to make, sell, import and export the Compounds, the Products and the Companion Diagnostics in all fields of use, except for certain hepatitis C virus use, or the Field, (ii) a non-exclusive, sublicensable license to make, import and export the Compounds, the Products and the Companion Diagnostics in the Field in the United States and (iii) a non-exclusive, sublicensable license to research and develop the Compounds, the Products and the Companion Diagnostics in the United States.

Subject to the terms and conditions of the Roche License Agreement, Roche granted us (i) an exclusive, sublicensable license to distribute, register and sell the Compounds and the Products in the United States, (ii) a non-exclusive, sublicensable license to research, develop, use, import, export and market the Compounds and the Products in the United States and (iii) a non-exclusive, sublicensable, worldwide (excluding the United States) license to research and develop the Compounds and the Products in the Field.

Subject to the terms and conditions of the Roche License Agreement, Roche and we will jointly develop certain Products including AT-527 for COVID-19 on a worldwide-basis and equally share the costs associated with such development activities. Atea remains responsible for, and alone will bear the costs associated with the development of AT-752 for dengue and other Retained Indications, as defined below.

Subject to the terms of the Roche License Agreement, we retain the sole right at our expense to develop, manufacture and commercialize the Compounds and the Products in the United States, and to develop and manufacture the Compounds and the Products outside of the United States, in each case, for the treatment of Dengue Fever, Japanese Encephalitis, West Nile Virus, Yellow Fever and/or Zika, or the Retained Indications. The parties will negotiate in good faith an amendment to the Roche License Agreement pursuant to which Roche may commercialize Products indicated for one or more Retained Indications outside of the United States, unless Roche offers such commercialization right to us. Neither Roche nor we may commercialize such Products outside of the United States until the parties agree to an amendment to the Roche License Agreement.

[Table of Contents](#)

Subject to the terms of the Roche License Agreement, we also have a one-time option to request that Roche co-promote the Products, other than for the Retained Indications, in the United States on a Product-by-Product basis, such option to be exercised by us prior to the expected regulatory approval of each applicable Product.

As partial consideration of the rights we granted to Roche under the Roche License Agreement, Roche will pay us an up front payment of \$350 million in November 2020. The Roche License Agreement further provides that Roche is obligated to pay us up to \$330 million in the aggregate upon the achievement of certain development or regulatory milestone events; up to \$320 million in the aggregate upon the achievement of certain sales-based milestone events; and tiered royalties based on annual net sales of the Products, such royalty percentages ranging between low double-digit and mid-twenties, subject to certain adjustments. Roche's obligation to pay us royalty payments will continue, on a country-by-country and Product-by-Product basis, until the later of (1) 10 years from the first commercial sale of a Product in a country and (2) expiration of the last to expire patent rights that we own or control containing a composition of matter claim covering such Product in such country.

The Roche License Agreement will remain in effect until the expiration of all payment obligations to us. Roche has the right to terminate the Roche License Agreement for convenience in its entirety or on a Product-by-Product or country-by-country basis, (x) upon three months' prior written notice if such notice is provided prior to the first commercial sale of the first Product and the parties are not conducting a certain prophylaxis study, in each case, pursuant to the terms of the Roche License Agreement, (y) if such notice is provided while the parties are conducting such prophylaxis study, upon the earlier of six months' prior written notice or the completion of such prophylaxis study, but in no event earlier than three months' prior written notice and (z) upon nine months' prior written notice if such notice is provided on or after the first commercial sale of the first Product pursuant to the terms of the Roche License Agreement. Each party has the right to terminate the Roche License Agreement (i) in its entirety or on a country-by-country basis for the other party's material breach of the terms of the Roche License Agreement, subject to a ninety-day cure period and (ii) for insolvency-related events involving the other party. Upon termination of the Roche License Agreement by Roche for the Company's material breach or insolvency, the rights and licenses granted by each party to the other party will terminate. Upon termination of the Roche License Agreement by Roche for convenience or by us for Roche's material breach, all rights and licenses granted by us to Roche will terminate, however, subject to the terms of the Roche License Agreement, we have the right to continue to develop and commercialize one or more terminated Products.

The Roche License Agreement also includes customary provisions regarding, among other things, confidentiality, intellectual property ownership, patent prosecution, enforcement and defense, representations and warranties, indemnification, insurance, and arbitration and dispute resolution.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of preclinical or clinical product candidates, nor do we have plans to develop or operate our own manufacturing operations in the future. Pursuant to the Roche License Agreement, we will rely on Roche to manufacture the commercial supply of AT-527. We currently rely upon third-party contract manufacturing organizations, or CMOs, to produce our product candidates for both preclinical and clinical use. Although we rely on CMOs, we also have personnel with extensive manufacturing experience that can oversee the relationship with our manufacturing partners. We believe that any materials required for the manufacture of our product candidates could be obtained from more than one source.

Competition

As a clinical-stage biopharmaceutical company, we face competition from a wide array of companies in the pharmaceutical and biotechnology industries. These include both small companies and large companies with

[Table of Contents](#)

much greater financial and technical resources and far longer operating histories than our own. We may also compete with the intellectual property, technology, and product development efforts of academic, governmental, and private research institutions.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing, and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of any product candidates that we develop, if approved, are likely to be their efficacy, safety, convenience, price, and the availability of reimbursement from government and other third-party payors. Our commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, and may commercialize products more quickly than we are able to.

We are aware of the following competitors in the areas that we are initially targeting:

SARS-CoV-2

Many therapies and vaccines are being investigated for the treatment of COVID-19, including:

- Remdesivir (Gilead Sciences, Inc.), a purine nucleotide prodrug, initially investigated for the treatment of Ebola virus. As of October 22, 2020, remdesivir has been approved or authorized for temporary use as a COVID-19 treatment in approximately 50 countries and has been approved by the FDA for the treatment of hospitalized adult and pediatric patients 12 years and older. Additionally, the FDA has granted an emergency use authorization for the treatment of hospitalized pediatric patients under the age of 12 with suspected or confirmed COVID-19.
- Favipiravir (Fujifilm Pharma Co., Ltd.), a nucleoside analog, first approved in Japan in 2014 for the treatment of emerging influenza strains and approved in 20[19/20] in Japan for the treatment of COVID-19.
- EIDD-2801 (Ridgeback Biotherapeutics LP/Merck & Co., Inc.), a nucleoside analog in Phase 2 clinical trials.
- REGN-COV2 (Regeneron Pharmaceuticals, Inc.), an antibody cocktail in a Phase 1/2/3 clinical trial.
- LY-CoV555 and LY-CoV016 (Eli Lilly and Co), a neutralizing antibody program for which Eli Lilly recently submitted an emergency use authorization request to the FDA.
- Additional companies working on investigational vaccines or treatments include Moderna, Inc., Inovio Pharmaceuticals, Inc., Vir Biotechnology Inc., Biogen Inc., Johnson & Johnson, Pfizer Inc., BioNTech SE - ADR, CanSino Biologics Inc., AbbVie Inc., Sanofi Pasteur Inc., AstraZeneca, Merck & Co., Inc., Eli Lilly and Co and Translate Bio Inc.

The potential treatments or vaccines for COVID-19 continues to evolve. The list above addresses the product candidates as of the date of this prospectus that we believe could be the most competitive with AT-527, but is not a comprehensive list of every treatment or vaccine that is in development for COVID-19.

HCV

FDA-approved treatments for patients with chronic HCV include Epclusa marketed by Gilead Sciences, Inc. and Mavyret, marketed by AbbVie Inc. We are also aware of an investigational agent for HCV, currently in Phase 2 testing, being developed by Cocrystal Pharma Inc.

Dengue Virus

At this time, there are no FDA- or EMA-approved treatments for dengue, and we are not aware of any potential therapeutics in development for treatment of dengue. Dengvaxia, marketed by Sanofi Pasteur, was approved in 2019 by the FDA for prevention of dengue in individuals ages nine to 16 with a laboratory-confirmed previous dengue infection and living in endemic areas. Takeda is also advancing TAK-003, which is in Phase 3 development, as a vaccine for dengue.

RSV

Supportive care is the most common course of care for RSV and includes oxygen, fluid management, bronchodilators, and corticosteroids. Ribavirin, approved in 1986, is used to treat severe cases of RSV infection, but carries significant side effects and risks associated with its use, especially in infants. Synagis (palivizumab), marketed by Swedish Orphan Biovitrum AB in the United States and AstraZeneca plc outside of the United States, is an FDA-approved, seasonal monoclonal antibody injection given monthly to help protect high-risk infants from severe RSV. Synagis is not approved as a treatment for RSV.

At this time, we are aware of investigational agents for the treatment of RSV being developed by Enanta Pharmaceuticals Inc., ReViral Ltd, and Ark Biosciences Inc.

Commercialization

Given the stage of development of our lead asset, we have not yet invested in a commercial infrastructure or distribution capabilities. We believe that the commercialization of AT-527 in the United States could be effected by a small Atea team across sales, marketing, reimbursement and other commercial activities. While we currently plan to establish our own commercial organization in the United States and potentially in other selected markets, we continue to consider and evaluate in each market the potential advantages and enhancements of our commercial capabilities that may be realized as a result of a collaboration between us and a pharmaceutical or other company, as we have recently done through the Roche License Agreement. In connection with AT-527, we have a one-time option to request Roche co-promote AT-527 in the United States.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our nucleotide therapeutic products for viral diseases, including our purine nucleotide compounds for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), hepatitis C (HCV) and dengue fever. We seek to protect our proprietary compounds and methods of treatment for viral diseases using our nucleotide compounds, alone and in combination with other therapeutic agents, in addition to dosage forms, dosing regimens and formulations for their administration. We also seek protection on the manufacturing process for the production of our nucleotide compounds. Our success also depends on our ability to operate without infringing, misappropriating or otherwise violating on the proprietary rights of others and to prevent others from infringing, misappropriating or otherwise violating our proprietary rights.

Our policy is to seek to protect our proprietary position by filing U.S. and foreign patent applications covering our proprietary technologies, inventions, and improvements that are important to the development and

[Table of Contents](#)

implementation of our business. In addition, we currently plan to seek patent term adjustments, restorations, and/or patent term extensions where applicable in the United States, Europe and other jurisdictions. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Additionally, we expect to benefit, where appropriate, from statutory frameworks in the United States, Europe and other countries that provide a period of regulatory data exclusivity to compensate for the time required for regulatory approval of our drug products.

As of September 30, 2020, we are the sole owner of eight patent families covering our product candidates and proprietary nucleotide compounds, which include composition of matter, pharmaceutical compositions, methods of use, and processes of manufacture as described in more detail below. Our owned patent estate as of September 30, 2020, on a worldwide basis, includes 117 granted or pending patent applications with five issued U.S. patents, one allowed U.S. non-provisional application, ten pending U.S. non-provisional applications, 11 pending U.S. provisional applications, two pending international patent applications filed under the Patent Cooperation Treaty, or PCT, and 88 pending or granted patent applications that have entered the national phase of prosecution in countries outside the United States.

The exclusivity terms of our patents depend upon the laws of the countries in which they are obtained. In the countries in which we currently file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. The term of a U.S. patent may be extended to compensate for the time required to obtain regulatory approval to sell a drug (a patent term extension) or by delays encountered during patent prosecution that are caused by the USPTO (referred to as patent term adjustment). For example, the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, permits a patent term extension for FDA-approved new chemical entity drugs of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review and diligence during the review process. Patent term extensions in the United States cannot extend the term of a patent beyond a total of 14 years from the date of product approval, only one patent covering an approved drug or its method of use may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. A similar kind of patent extension, referred to as a Supplementary Protection Certificate, is available in Europe. Legal frameworks are also available in certain other jurisdictions to extend the term of a patent. We currently intend to seek patent term extensions on any of our issued patents in any jurisdiction where we have a qualifying patent and the extension is available; however, there is no guarantee that the applicable regulatory authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. Further, even if our patent is extended, the patent, including the extended portion of the patent, may be held invalid or unenforceable by a court of final jurisdiction in the United States or a foreign country.

Current issued patents and patent applications covering the composition of matter for our present clinical candidates AT-511, AT-527, AT-281 (the free base of AT-752), and AT-752 will expire on dates ranging from 2036 to 2038, if the applications are issued and held valid by a court of final jurisdiction if challenged. Current patent applications covering the use of AT-511 and AT-527 for the treatment of SARS-CoV-2 will expire on dates ranging from 2037 to 2041, if the applications (including non-provisional applications filed on the basis of provisional applications) are issued and held valid by a court of final jurisdiction if challenged. Current issued patents and patent applications covering the use of AT-511 and AT-527 for the treatment of HCV will expire on dates ranging from 2036 to 2039, if the applications are issued and held valid by a court of final jurisdiction if challenged. Current patent applications covering the use of AT-281 and AT-752 for the treatment of dengue fever will expire on a date in 2037, if the applications are issued and held valid by a court of final jurisdiction if challenged.

Current patent applications covering the composition of matter for our present HCV combination drug clinical candidate AT-787 will expire on a date in 2039, if the applications are issued and held valid by a court of final

[Table of Contents](#)

jurisdiction if challenged. Current patent applications covering the use of AT-787 for the treatment of HCV will expire on dates ranging from 2036 to 2039, if the applications are issued and held valid by a court of final jurisdiction if challenged.

However, any of our patents, including patents that we may rely on to protect our market for approved products, may be held invalid or unenforceable by a court of final jurisdiction. Alternatively, we may decide that it is in our interest to settle a litigation in a manner that affects the term or enforceability of our patent. Changes in either the patent laws or in interpretations of patent laws in the United States and other jurisdictions may diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that have been or may be granted on our patents or on third-party patents. The pharmaceutical and biotechnology industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to obtain and maintain our proprietary position for our nucleotide compounds and the use of these compounds will depend on our success in enforcing patent claims that have been granted or may grant. We do not know whether any of the pending patent applications that we have filed or may file or license from third parties will result in the issuance of any additional patents. The issued patents that we own or may receive in the future may be challenged, invalidated, or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize drugs with similar mechanisms of action and/or duplicate our methods of treatments or strategies without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent. For more information regarding risks relating to intellectual property, see “Risk Factors—Risks Related to Intellectual Property.”

Our patent families, as of September 30, 2020, are further described below.

AT-511 and AT-527

We own a first patent family that describes AT-511 or a pharmaceutically acceptable salt thereof (for example, AT-527), pharmaceutical compositions of AT-511 or the pharmaceutical salts thereof, and methods to treat HCV using AT-511 or a salt thereof. This family consists of four issued U.S. patents (U.S. Pat. Nos. 9,828,410; 10,000,523; 10,005,811; and 10,239,911), on allowed U.S. application and four pending U.S. applications covering AT-511 or a pharmaceutically acceptable salt thereof and its pharmaceutical compositions. This patent family is now also in the national stage of prosecution in the African Regional Intellectual Property Organization, or ARIPO, Australia, Brazil, Canada, China, Colombia, the Eurasian Patent Office, or EAPO, Egypt, the European Patent Office, or EPO, Georgia, Hong Kong, Indonesia, Israel, India, Japan, Korea, Mexico, Malaysia, Nigeria, New Zealand, the Philippines, Russia, Saudi Arabia, Singapore, Thailand, Vietnam, Ukraine, South Africa, and the United Arab Emirates. The expected year of expiration for this patent family, where issued, valid and enforceable, is 2036, without regard to any extensions, adjustments, or restorations of term that may be available under national law.

We also own a second patent family that specifically covers AT-527, pharmaceutical compositions, and methods to treat HCV using AT-527. This family includes one issued U.S. patent (U.S. Pat. No. 10,519,186) and two pending U.S. applications covering AT-527, pharmaceutical compositions, and methods to treat HCV using AT-527. This family is currently in the national phase of prosecution in Argentina, ARIPO, Australia, Brazil, Canada, China, Colombia, the EAPO, the EPO, Georgia, Hong Kong, Indonesia, Israel, India, Japan, Korea, Mexico, Malaysia, Nigeria, New Zealand, the Philippines, Russia, Singapore, Taiwan, Thailand, Vietnam, Ukraine,

[Table of Contents](#)

Uzbekistan, and South Africa. The expected year of expiration for this patent family, if issued, valid and enforceable, is 2038, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws.

We own a third patent family that discloses methods for the treatment of SARS-CoV-2 using AT-511 or AT-527. This family includes seven provisional U.S. applications. The expected year of expiration for patents issued from non-provisional patent applications filed on the basis of these provisional patent applications, if valid and enforceable, is 2041, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws. We have recently filed a U.S. normal application with the U.S. PTO under its COVID-19 Prioritized Examination Pilot Program to advance out of turn patent applications covering methods to treat COVID-19 that are currently under review by the FDA. Our Petition was granted by the PTO on September 23, 2020.

We own a fourth patent family that discloses the use of AT-511 or a pharmaceutically acceptable salt thereof for the treatment or prevention of a positive-stranded RNA virus infection, including a *Coronaviridae* viral infection. This family consists of two pending U.S. applications and is currently in the national phase of prosecution in Australia, Brazil, Canada, China, the EAPO, the EPO, Hong Kong, Indonesia, Japan, Korea, Malaysia, Nigeria, Russia, Singapore, Thailand, Vietnam, and South Africa. The expected year of expiration for this patent family, if issued, valid and enforceable, is 2037, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws.

We own a fifth patent family that discloses the use of AT-511 and AT-527 for the treatment of HCV in patients with cirrhosis of the liver. This family includes one international application filed under the PCT (PCT/US19/26837), one patent application filed in Taiwan, and one application filed in Europe. The expected year of expiration for this patent family, if issued, valid and enforceable, is 2039, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws.

We also own a sixth patent family that discloses methods for manufacturing AT-511 and AT-527. This family consists of two provisional U.S. applications. The expected year of expiration for patents issued from non-provisional patent applications filed on the basis of these provisional patent applications, if valid and enforceable, is 2041, without regard to adjustments of term that may be available under U.S. or other national laws.

We also own a seventh patent family that discloses new commercial scale processes for the manufacture of AT-511 and AT-527. This family consists of two U.S. provisional applications. The expected year of expiration for patents issuing from these non-provisional patent applications, if valid and enforceable, is 2041, without regard to any adjustments of term that may be available under U.S. or other national law.

AT-787

We own an eighth patent family that discloses the combination of AT-511 or AT-527 and AT-777 (i.e., AT-787) for the treatment of HCV. This family includes one pending U.S. application, one international application filed under the PCT (PCT/US19/64522), one patent application in Taiwan, and one patent application in Argentina. The expected year of expiration for this patent family, if issued, valid and enforceable, is 2039, without regard to any extensions, adjustments, or restorations of term that may be available under U.S. or other national laws.

AT-281 and AT-752

The first patent family described above also describes AT-281, a pharmaceutically acceptable salt thereof (for example, AT-752) and pharmaceutical compositions of AT-281 or a pharmaceutical salt thereof and their use to treat HCV infection.

[Table of Contents](#)

The second patent family described above also describes AT-752 and pharmaceutical compositions of AT-752. One of these pending U.S. application in this patent family covers AT-752 and pharmaceutical compositions of AT-752.

The fourth patent family described above also includes a disclosure of the use of AT-281 or a pharmaceutically acceptable salt thereof for the treatment or prevention of an RNA viral infection, including dengue fever, yellow fever, and Zika virus in addition to the treatment and prevention of a *Coronaviridae* viral infection. Therefore, we have three patent families that describe AT-281 or AT-752 and methods of treatment for viral infections using AT-281 or AT-752.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the new drug application, or NDA, process before it may be legally marketed in the United States.

U.S. drug development process

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice requirements, or GCPs to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCPs; and

[Table of Contents](#)

- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an IND product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. Once submitted, the IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1:* The product candidate is initially introduced into healthy human subjects, in some cases, patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- *Phase 2:* The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3:* The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

[Table of Contents](#)

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

U.S. review and approval process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is

[Table of Contents](#)

submitted to FDA because the FDA has approximately two months to make a “filing” decision after it the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations or restrictions on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

[Table of Contents](#)

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited development and review programs

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A drug is eligible for priority review if it is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or effectiveness compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the predicted clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required clinical trials, or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as “breakthrough therapies” that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a “breakthrough therapy” if the product is intended, alone or in

[Table of Contents](#)

combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, 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.

Tropical Disease Priority Review Voucher Program

In 2007, Congress authorized the FDA to award priority review vouchers, or PRVs, to sponsors of certain tropical disease product applications. The FDA's Tropical Disease Priority Review Voucher Program is designed to encourage development of new drug and biological products for the prevention and treatment of certain tropical diseases affecting millions of people throughout the world. Under this program, a sponsor who receives an approval for a drug or biologic for the prevention or treatment a tropical disease that meets certain criteria may qualify for a PRV that can be redeemed to receive priority review of a subsequent NDA or Biologics License Application, or BLA, for a different product. The sponsor of a tropical disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor of an NDA or BLA. The FDCA does not limit the number of times a priority review voucher may be transferred before the voucher is used.

For a product to qualify for a PRV, (i) the sponsor must request approval of the product for the prevention or treatment of a "tropical disease" listed in Section 524 of the FDCA, (ii) the product must otherwise qualify for priority review, and (iii) the product must contain no active ingredient (including any salt or ester of an active ingredient) that has been approved by the FDA in any other NDA or BLA. The Food and Drug Administration Reauthorization Act of 2017 made further changes to the eligibility criteria for receipt of a tropical disease PRV under this program. Specifically, applications submitted after September 30, 2017 must also contain reports of one or more new clinical investigations (other than bioavailability studies) that were essential to the approval of the application and conducted or sponsored by the sponsor. We are currently developing AT-752 for the treatment of Dengue, which is listed in Section 524 of the FDCA as a disease qualifying for a tropical disease PRV. Accordingly, if AT-752 is approved by the FDA for the prevention or treatment of Dengue, we may receive a tropical disease PRV, provided that AT-752 otherwise meets the statutory criteria for receipt.

Post-approval requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products.

Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state

[Table of Contents](#)

agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon drug manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict marketers' communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Marketing exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, pricing reporting, data privacy and security, and physician payment transparency laws and regulations as well as similar foreign laws in the jurisdictions outside the United States. Violation of any of such laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement fines, additional reporting requirements and oversight obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and/ or imprisonment.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we may seek regulatory approval. Sales in the United States will depend, in part, on the availability of sufficient

[Table of Contents](#)

coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by third-party payors.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. In the United States, there is no uniform policy among payors for coverage or reimbursement. Decisions regarding whether to cover any of a product, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. 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 can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Additionally, decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

U.S. Healthcare Reform

In the United States, there has been, and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates.

Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a 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; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented 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

[Table of Contents](#)

injected; expanded eligibility criteria for Medicaid programs; created 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 established a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There remain judicial and political challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017 (Tax Act) includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit affirmed the District Court’s decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, although it remains unclear how and when the Court will make a decision. In addition, it is unclear how any other efforts to repeal, replace or challenge the ACA will impact the law.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2029 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was signed into law on March 27, 2020 and suspended these reductions from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic, and extended the sequester by one year, through 2030. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, the current U.S. administration’s budget proposal for the fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. The Trump Administration previously released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of pharmaceutical products paid by consumers. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

[Table of Contents](#)

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Employees

As of September 30, 2020, we had 19 full-time employees, including eight employees with M.D. or Ph.D. degrees. Of these full-time employees, 11 employees are engaged in research and development activities. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Facilities

Our principal office is located at 125 Summer Street, Boston, Massachusetts, where we lease 5,634 square feet of office space. We lease this space under a lease agreement, as amended, that terminates on July 31, 2022. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Legal Proceedings

We are not subject to any material legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of the date of this prospectus.

Name	Age	Position
Executive Officers		
Jean-Pierre Sommadossi, Ph.D.	64	President and Chief Executive Officer and Chairman of the Board of Directors
Andrea Corcoran	58	Chief Financial Officer, Executive Vice President, Legal and Secretary
Janet Hammond, M.D., Ph.D.	60	Chief Development Officer
Maria Arantxa Horga, M.D.	51	Acting Chief Medical Officer
John Vavricka	56	Chief Commercial Officer
Wayne Foster	52	Senior Vice President, Finance and Administration
Directors		
Franklin Berger (1)(2)	71	Director
Isaac Cheng, M.D.	45	Director
Barbara Duncan (1)(3)	55	Director
Andrew Hack, M.D., Ph.D. (1)	47	Director
Bruno Lucidi (2)	60	Director
Polly A. Murphy, D.V.M., Ph.D. (3)	56	Director
Bruce Polsky, M.D. (2)(3)	66	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Executive Officers

Jean-Pierre Sommadossi, Ph.D., is the founder of our company and has served as our President and Chief Executive Officer and as Chairman of our Board since July 2012. Prior to that, he co-founded and held several roles at Idenix Pharmaceuticals, Inc., a biopharmaceutical company, from 1998 to 2010, including Principal Founder and Chief Executive Officer and Chairman. Dr. Sommadossi also co-founded Pharmasset, a biopharmaceutical company, in 1998. Dr. Sommadossi has also served as the Chairman of the board of directors of Kezar Life Sciences, Inc., a biopharmaceutical company, since June 2015, Vice Chair of the board of directors of Rafael Pharmaceuticals, Inc. a biopharmaceutical company, since 2016, Chairman of the board of directors of Panchrest, Inc., a marketing authorized representative in healthcare, since 2013, Chairman of the board of directors of PegaOne, a biopharmaceutical company since 2019, a member the board of directors of The BioExec Institute and as member of the Harvard Medical School Discovery Council since 2010. Dr. Sommadossi received his Ph.D. and Pharm.D. degrees from the University of Marseilles in France. We believe that

[Table of Contents](#)

Dr. Sommadossi's extensive scientific, operational, strategic and management experience in the biotech industry qualifies him to serve on our Board.

Andrea Corcoran has served as our Chief Financial Officer since October 2020, our corporate Secretary since September 2014 and our Executive Vice President, Legal and Administration since December 2013. Prior to joining us, Ms. Corcoran served as Senior Vice President, Strategy and Finance at iBio, Inc., a biotechnology company, from 2011 to 2012, as General Counsel and Secretary at Tolerx, Inc., a biopharmaceutical company, from 2007 to 2011, and as Executive Vice President of Idenix Pharmaceuticals, Inc. from 1998 to 2007. Ms. Corcoran received her J.D. from Boston College Law School and her B.S. from Providence College.

Janet Hammond, M.D., Ph.D., has served as our Chief Development Officer since August 2020. Prior to joining us, Dr. Hammond served at AbbVie, Inc., a biopharmaceutical company, from November 2016 to August 2020 as Vice President and Therapeutic Area Head for General Medicine and Infectious Disease Development and at F. Hoffmann-La Roche from March 2011 to November 2016 as Senior Vice President, Global Head of Infectious Diseases and Head of Pharmaceutical Research and Early Development China. Dr. Hammond received her M.D. and Ph.D. from the University of Cape Town, South Africa, and her Sc.M. in Clinical Investigation from Johns Hopkins University School of Hygiene and Public Health.

Maria Arantxa Horga, M.D., has served as our Acting Chief Medical Officer since October 2020 and as Executive Vice President, Clinical Sciences since August 2020. Prior to joining us, Dr. Horga served as Vice President, Pharmacovigilance and Medical Affairs at Biohaven Pharmaceuticals from October 2019 to August 2020. Prior to that, Dr. Horga served as Vice President, Global Head of Clinical Program Execution, Site Head of the Roche NY Innovation Center from July 2017 to August 2019, and as Global Head of Translational Medicine, Infectious Diseases at F. Hoffmann-La Roche from 2012 to 2016. Dr. Horga received her M.D. from the Santander School of Medicine, and completed her residency in Pediatrics and a fellowship in Pediatric Infectious Diseases at the Mount Sinai School of Medicine.

John Vavricka has served as our Chief Commercial Officer since October 2018. Prior to joining us, Mr. Vavricka cofounded Biothea Pharma, Inc., a biotechnology company, in 2015, and was the Founder, Chief Executive Officer and President of Iroko Pharmaceuticals, Inc., a global pharmaceuticals company, from 2007 to 2015. Mr. Vavricka received his B.S. from Northwestern University.

Wayne Foster has served as our Senior Vice President, Finance and Administration since December 2019. Prior to joining us, Mr. Foster served as Vice President of Finance at Mersana Therapeutics, Inc., a biopharmaceutical company, from January 2012 to September 2019. Mr. Foster received his B.B.A. from the University of Massachusetts Amherst.

Directors

Franklin Berger has served as a member of our Board since September 2019. Mr. Berger is a consultant to biotechnology industry participants, including major biopharmaceutical firms, mid-capitalization biotechnology companies, specialist asset managers and venture capital companies, providing business development, strategic, financing, partnering, and royalty acquisition advice. Mr. Berger is also a biotechnology industry analyst with experience in capital markets and financial analysis and a Founder and Managing Director at FMB Research. Mr. Berger has also served on the board of directors of BELLUS Health, Inc. since May 2010, ESSA Pharma Inc. since March 2015, Proteostasis Therapeutics, Inc. since February 2016, Kezar Life Sciences, Inc. since January 2016, and Five Prime Therapeutics, Inc. since October 2014. Mr. Berger previously served on the board of directors of Tocagen, Inc. from October 2014 to June 2020. Mr. Berger received his B.A. and M.A. from Johns Hopkins University and his M.B.A. from Harvard Business School. We believe that Mr. Berger's financial background and experience as an equity analyst in the biotechnology industry combined with his experience serving on the boards of directors of multiple public companies qualifies him to serve on our Board.

Table of Contents

Isaac Cheng, M.D., has served as a member of our Board since March 2019. Dr. Cheng is an investment professional at the Morningside Technology Advisory, LLC, a division of the Morningside Group, a group that invests in venture capital and private equity opportunities. Dr. Cheng served on the board of directors of NuCana PLC from May 2017 to March 2020 and Liquidia Technologies, Inc., from January 2010 to January 2018. Dr. Cheng received his M.D. and B.S. from the Tufts University School of Medicine. We believe Dr. Cheng is qualified to serve on our Board due to his financial expertise, experience as a venture capitalist, industry experience and his experience in serving on the board of directors of public and private life sciences companies.

Barbara Duncan has served as a member of our Board since October 2020. Ms. Duncan served at Intercept Pharmaceuticals, Inc. as Chief Financial Officer and Treasurer from May 2009 to June 2016. Ms. Duncan serves on the board of directors of Jounce Therapeutics, Inc. since June 2016, Adaptimmune Therapeutics plc since June 2016, ObsEva S.A. since November 2016, and Ovid Therapeutics, Inc. since June 2017. Previously, Ms. Duncan served on the boards of directors of Immunomedics, Inc. from March 2019 to October 2020, Innoviva, Inc., from November 2016 through April 2018, and Aevi Genomic Medicine, Inc., from June 2015 through January 2020. Ms. Duncan received her B.A. from Louisiana State University and her M.B.A. from the Wharton School, University of Pennsylvania. We believe Ms. Duncan is qualified to serve on our Board due to her experience in the biotechnology industry and with public companies.

Andrew Hack, M.D., Ph.D., has served on our Board since May 2020. Dr. Hack is a Partner and Managing Director of Bain Capital Life Sciences, a private equity fund that invests in biopharmaceutical, specialty pharmaceutical, medical device, diagnostics, and enabling life science technology companies globally. From July 2015 to March 2019, Dr. Hack served as Chief Financial Officer of Editas Medicine, Inc. From May 2011 to June 2015, Dr. Hack was a portfolio manager at Millennium Management LLC, an institutional asset manager, where he ran a healthcare fund focused on biotechnology, pharmaceutical, and medical device companies. From December 2008 to May 2011, Dr. Hack was a healthcare analyst at HealthCor Management, L.P., a registered investment advisor. Previously, Dr. Hack was Director of Life Sciences and co-founder of Reify Corporation, a life science tools and drug discovery company. Dr. Hack also serves as a director of Affinivax, Inc., Allena Pharmaceuticals, Inc., BCLS Acquisition Corp., Dynavax Technologies, Inc., Imperative Care, Inc., JenaValve Technology, Inc. and Mersana Therapeutics, Inc. Dr. Hack received his B.A. in biology with special honors from the University of Chicago, where he also received his M.D. and Ph.D. We believe Dr. Hack is qualified to serve on our Board due to his extensive financial and investment experience in the life sciences industry.

Bruno Lucidi has served as a member of our Board since September 2014. Mr. Lucidi is a Life Sciences Expert at Wallonia Trade and Foreign Investment Agency. From October 2017 to September 2019, Mr. Lucidi was Chief Executive Officer at AgenTus Therapeutics, a pre-clinical stage biopharmaceutical company. Mr. Lucidi was trained in Oncology at the Gustave Roussy Institute, Villejuif, France, in Marketing and Strategic Management of Companies at the Ecole Supérieure de Commerce, Paris, France, and in Finance, Merger and Acquisitions at the Investment Banking Institute in New York. We believe Mr. Lucidi is qualified to serve on our Board due to his extensive experience in the life sciences industry.

Polly A. Murphy, D.V.M., Ph.D. has served as a member of our Board since August 2020. Dr. Murphy has served as Chief Business Officer at UroGen Pharma, Inc. since August 2020. Since September 2008, Dr. Murphy has served at Pfizer, Inc., most recently as Vice President and Head of Commercial Development Pfizer Oncology Business Unit from January 2019 to August 2020, Vice President and Head of Global Marketing and Commercial Development Pfizer Oncology Business Unit from June 2017 to December 2018 and as Vice President and Head of Strategy and Business Development for Pfizer China from November 2013 to May 2018. Dr. Murphy received her D.V.M. and Ph.D. from Iowa State University. We believe Dr. Murphy is qualified to serve on our Board due to her experience in the pharmaceutical industry in business development and commercialization.

[Table of Contents](#)

Bruce Polsky, M.D., has served as a member of our Board since November 2014. Dr. Polsky is the chair of the Department of Medicine at NYU Winthrop Hospital in Mineola, New York, where he has practiced since 2015. He also serves as professor and Chair of the Department of Medicine at NYU Long Island School of Medicine and as an Associate Dean at NYU Long Island School of Medicine. Dr. Polsky is a leading clinical virologist who played an active role in clinical investigations of HIV/AIDS, HBV, HCV and other viral infections. From 1998 to 2015, Dr. Polsky was at Mount Sinai St. Luke's and Mount Sinai Roosevelt Hospitals, where he served as Chair of the Department of Medicine and as Chief of the Division of Infectious Diseases, among other positions. Dr. Polsky received his M.D. from Wayne State University. We believe Dr. Polsky is qualified to serve on our Board due to his extensive clinical experience in the life sciences industry.

Board Composition and Election of Directors

Director Independence

Our board consists of eight members. Our board of directors has determined that, of these eight directors, Franklin Berger, Isaac Cheng, M.D., Barbara Duncan, Andrew Hack, M.D., Ph.D., Bruno Lucidi, Polly A. Murphy, D.V.M., Ph.D. and Bruce Polsky, M.D. do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors and director nominee is "independent" as that term is defined under the rules of The Nasdaq Stock Market LLC, or the Nasdaq Rules. The Nasdaq Rules' independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by the Nasdaq Rules, our board of directors has made a subjective determination as to each independent director and director nominee that no relationships exists that, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed information provided by the directors, director nominee and us with regard to each director's and director nominee's business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors, director nominee or executive officers.

Classified Board of Directors

In accordance with our restated certificate of incorporation that will go into effect upon the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Jean-Pierre Sommadossi, Ph.D., Andrew Hack, M.D., Ph.D. and Franklin Berger, and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be Bruce Polsky, M.D., Bruno Lucidi and Polly Murphy, D.V.M., Ph.D., and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be Barbara Duncan and Isaac Cheng, M.D., and their terms will expire at the third annual meeting of stockholders following this offering.

Our restated certificate of incorporation that will go into effect upon the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes

so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock entitled to vote in the election of directors.

Board Leadership Structure

Our board of directors is currently chaired by Jean-Pierre Sommadossi, Ph.D. Our corporate governance guidelines provide that, if the chairman of the board is a member of management or does not otherwise qualify as independent, the independent directors of the board may elect a lead director. Franklin Berger currently serves as our lead director. The lead director's responsibilities include, but are not limited to: presiding over all meetings of the board of directors at which the chairman is not present, including any executive sessions of the independent directors; approving board meeting schedules and agendas; and acting as the liaison between the independent directors and the chief executive officer and chairman of the board. Our corporate governance guidelines further provide the flexibility for our board of directors to modify our leadership structure in the future as it deems appropriate.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

Board Committees

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that has been approved by our board of directors. Upon our listing on The Nasdaq Global Select Market, each committee's charter will be available under the Corporate Governance section of our website at www.Ateapharma.com. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

Audit Committee

The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;

Table of Contents

- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by Securities Exchange Commission, or SEC, rules.

The members of our audit committee are Barbara Duncan, Franklin Berger and Andrew Hack, M.D., Ph.D. Barbara Duncan serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the Nasdaq Rules. Our board of directors has determined that Barbara Duncan, Andrew Hack, M.D., Ph.D. and Franklin Berger meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq Rules. Our board of directors has determined that Barbara Duncan is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq Rules.

Compensation Committee

The compensation committee's responsibilities include:

- reviewing and approving, or recommending for approval by the board of directors, the compensation of our CEO and our other executive officers;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," to the extent required; and
- preparing the annual compensation committee report required by SEC rules, to the extent required.

The members of our compensation committee are Franklin Berger, Bruno Lucidi and Bruce Polsky, M.D. Franklin Berger serves as the chairperson of the committee. Our board of directors has determined that each of Franklin Berger, Bruno Lucidi and Bruce Polsky, M.D. is independent under the applicable Nasdaq Rules, including the Nasdaq Rules specific to membership on the compensation committee, and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee's responsibilities include:

- identifying individuals qualified to become board members;

[Table of Contents](#)

- recommending to our board of directors the persons to be nominated for election as directors and to each board committee;
- developing and recommending to our board of directors corporate governance guidelines, and reviewing and recommending to our board of directors proposed changes to our corporate governance guidelines from time to time; and
- overseeing a periodic evaluation of our board of directors.

The members of our nominating and corporate governance committee are Polly A. Murphy, D.V.M., Ph.D., Barbara Duncan and Bruce Polsky, M.D. Polly A. Murphy, D.V.M., Ph.D. serves as the chairperson of the committee. Our board of directors has determined that Polly A. Murphy, D.V.M., Ph.D., Barbara Duncan and Bruce Polsky, M.D. are independent under the applicable Nasdaq Rules and the SEC rules and regulations.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee is or has been our current or former officer or employee. None of our executive officers served as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity, one of whose executive officers served as a director or member of our compensation committee.

Code of Ethics and Code of Conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Upon our listing on The Nasdaq Global Select Market, our code of business conduct and ethics will be available under the Corporate Governance section of our website at www.Ateapharma.com. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the 2019 Summary Compensation Table below. In 2019, our “named executive officers” and their positions were:

- Jean-Pierre Sommadossi, Ph.D., Chairman and Chief Executive Officer;
- Andrea Corcoran, Chief Financial Officer and Executive Vice President, Legal; and
- Daniel Geffken, former Interim Chief Financial Officer.

Mr. Geffken resigned his position as our Interim Chief Financial Officer in October 2020, and was succeeded by Ms. Corcoran. This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

2019 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2019.

Name and Principal Position	Year	Salary (\$)	Bonus \$(1)	Option Awards \$(2)	Non-Equity Incentive Plan Compensation (\$)	All Other Compensation \$(3)	Total (\$)
Jean-Pierre Sommadossi Founder, Chairman and Chief Executive Officer	2019	400,000	160,000	251,080	—	—	811,080
Andrea Corcoran Chief Financial Officer and Executive Vice President, Legal	2019	290,000	75,000	75,324	—	—	440,324
Daniel Geffken Former Interim Chief Financial Officer	2019	—	—	101,426	—	145,000	246,426

- (1) Amounts represent the discretionary annual bonus paid in recognition of 2019 performance. Refer to “—2019 Bonuses” below for additional information.
- (2) Amounts represent the aggregate grant date fair value of stock options issued during 2019, computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of these options in Note 9 to the annual consolidated financial statements included in this prospectus.
- (3) For Mr. Geffken, amount represents fees paid to Danforth for Mr. Geffken’s services pursuant to a consulting agreement between the Company and Danforth. Mr. Geffken is a founder of Danforth. Mr. Geffken resigned his position as our Interim Chief Financial Officer in October 2020, and was succeeded by Ms. Corcoran. Refer to “—Executive Compensation Arrangements” below for additional information regarding the consulting agreement.

NARRATIVE TO SUMMARY COMPENSATION TABLE

2019 Salaries

Each of Dr. Sommadossi and Ms. Corcoran receives a base salary to provide a fixed component of compensation reflecting the executive’s skill set, experience, role and responsibilities. Mr. Geffken was not an employee of the Company and therefore did not receive a base salary from the Company. Annual base salaries are reviewed

[Table of Contents](#)

periodically by the board of directors. Effective January 1, 2019, following its annual review, the board of directors increased the base salaries for the named executive officers as follows:

- Dr. Sommadossi's base salary was increased from \$350,000 to \$400,000 per year; and
- Ms. Corcoran's base salary was increased from \$242,000 to \$290,000 per year.

Effective January 1, 2020, following its annual review, the board of directors increased the base salaries for the named executive officers as follows:

- Dr. Sommadossi's base salary was increased from \$400,000 to \$412,000 per year; and
- Ms. Corcoran's base salary was increased from \$290,000 to \$298,700 per year.

2019 Bonuses

Our board of directors may elect to provide annual bonuses to each of Dr. Sommadossi and Ms. Corcoran based on the executive's or our annual performance. In December 2019, our board of directors evaluated the performance of Dr. Sommadossi and Ms. Corcoran for fiscal year 2019 and, in recognition of the Company's and each executive's performance, elected to pay each of them the respective discretionary cash bonus set forth above in the 2019 Summary Compensation Table.

Equity Compensation

In 2019, we granted stock options to our employees and certain other service providers, including our named executive officers, as the long-term incentive component of our compensation program. Our stock options generally allow employees to purchase shares of our common stock at a price per share equal to the fair market value of our common stock on the date of grant, as determined by the board of directors.

The following table sets forth the stock options granted to our named executive officers in during 2019.

Named Executive Officer	2019 Stock Options Granted
Jean-Pierre Sommadossi	200,000
Andrea Corcoran	60,000
Daniel Geffken	116,891

These stock options were granted under our 2013 Equity Incentive Plan which we refer to as the Prior Plan, with exercise prices equal to \$1.85 for Dr. Sommadossi and Ms. Corcoran and \$1.43 for Mr. Geffken, which the board of directors determined to be the fair market value of our common stock on the date of grant. The option granted to each of Dr. Sommadossi and Ms. Corcoran vests in 48 equal monthly installments on the final day of each month following the date of grant, with the first installment vesting on December 31, 2019, subject to continued employment through each applicable vesting date. The option granted to Mr. Geffken vests in 24 monthly installments over the two years following the date of grant, subject to the consulting agreement between Danforth and the Company remaining in effect. Refer to "—Executive Compensation Arrangements" below for additional information regarding the consulting agreement.

In connection with this offering, we adopted a 2020 Omnibus Incentive Plan, referred to below as the 2020 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of the Company and certain of its affiliates and to enable the Company and certain of its affiliates to obtain and retain services of these individuals, which we consider to be essential to our long-term success. Following the effective date of the 2020 Plan, we will not make any further grants under the Prior Plan. However, the Prior Plan will continue to govern the terms and conditions of the outstanding awards previously granted under it. For additional information about the 2020 Plan, please see the section titled "Incentive Compensation Plans" below.

Other Elements of Compensation

During their employment, our named executive officers are eligible to participate in our employee benefit plans and programs, including medical and dental benefits, to the same extent and on the same terms as our other full-time employees generally. As a non-employee service provider of the Company, Mr. Geffken did not participate in our employee benefit plans and programs.

Outstanding Equity Awards at 2019 Fiscal Year-End

The following table summarizes the outstanding equity incentive plan awards for each named executive officer as of December 31, 2019.

Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Awards	
				Option Exercise Price (\$)	Option Expiration Date
Jean-Pierre Sommadossi	12/13/2019(1)	4,167	195,833	1.85	12/12/2029
	12/14/2018(1)	54,167	145,833	1.43	12/14/2028
	12/8/2017(2)	323,889	61,111	1.53	12/8/2027
Andrea Corcoran	12/9/2016(3)	300,000		1.24	12/9/2026
	12/13/2019(1)	1,250	58,750	1.85	12/12/2029
	12/4/2018(1)	16,250	43,750	1.43	12/14/2028
	12/8/2017(4)	41,667	18,333	1.53	12/8/2027
Daniel Geffken	12/9/2016(4)	60,000		1.24	12/9/2026
	7/31/2019(5)	24,352	92,539	1.43	7/30/2029

- (1) The option vests in 48 equal monthly installments beginning December 31 of the year of grant, subject to continued employment through each applicable vesting date.
- (2) The option was vested as to 185,000 shares on the date of grant and the remaining portion of the option vests in 36 equal monthly installments beginning December 31 of the year of grant, subject to continued employment through each applicable vesting date.
- (3) The option was vested as to 75,000 shares on the date of grant and the remaining portion of the option vests in 36 equal monthly installments beginning December 31 of the year of grant, subject to continued employment through each applicable vesting date.
- (4) The option vests in 36 equal monthly installments beginning December 31 of the year of grant, subject to continued employment through each applicable vesting date.
- (5) The option vests in 24 equal monthly installments beginning at the end of each one-month period following the date of grant, subject to the consulting agreement between Danforth and the Company remaining in effect through each such vesting date. If the Company terminates the consulting agreement without cause prior to the first anniversary of the date of grant, the vesting of any unvested portion of the option will immediately accelerate, vest and become exercisable.

Executive Compensation Arrangements

During 2019, neither Dr. Sommadossi nor Ms. Corcoran was a party to an agreement providing for any severance, termination or change in control benefits or payments.

During 2019, we were party to a consulting agreement with Danforth, or the Danforth Agreement, pursuant to which we paid Danforth for services rendered by certain of its consultants, including Mr. Geffken. The Danforth Agreement is terminable by either party other than for cause upon 60 days' prior written notice to the other party. On October 1, 2020, we notified Danforth that the Danforth Agreement would terminate upon expiration of the 60 day notice period, and Mr. Geffken resigned his position as our Interim Chief Financial Officer with immediate effect.

Compensation Changes in Connection with Initial Public Offering

In October 2020, in anticipation of and subject to this offering, our board of directors approved certain changes to Dr. Sommadossi's and Ms. Corcoran's compensation arrangements, as described in this section below.

Annual Base Salaries

Our board of directors approved an increase in Dr. Sommadossi's annual base salary to \$565,000 and Ms. Corcoran's annual base salary to \$465,000, effective on the date of this offering.

Target Bonuses

Our board of directors approved a target bonus percentage for Dr. Sommadossi equal to 55% of annual base salary and for Ms. Corcoran equal to 40% of annual base salary, effective on the date of this offering.

Employment Agreements

Our board of directors approved, and we entered into, employment agreements with Dr. Sommadossi and Ms. Corcoran that will become effective on date of this offering.

Under the employment agreements, if we terminate Dr. Sommadossi's or Ms. Corcoran's employment without "cause" or the named executive officer resigns for "good reason" other than in connection with a change in control of the Company, subject to the execution and non-revocation of a separation agreement and release with the Company and compliance with restrictive covenants contained therein, the named executive officer will be entitled to receive (i) continued payment of base salary for 18 months for Dr. Sommadossi or 12 months for Ms. Corcoran, (ii) any unpaid bonus earned for the year prior to the year of termination and (iii) direct payment of or reimbursement for COBRA premiums, less the amount the named executive officer would have paid for coverage as an active employee, for up to 18 months for Dr. Sommadossi and 12 months for Ms. Corcoran. If such a qualifying termination occurs on or within 12 months following the date of a change in control of the Company or, for Dr. Sommadossi, during the 3 month period prior to the date of a change in control of the Company, subject to the execution and non-revocation of a separation agreement and release with the Company and compliance with restrictive covenants contained therein, the named executive officer will be entitled to receive, in lieu of the payments and benefits described above, (a) continued payment of the named executive officer's base salary for 24 months for Dr. Sommadossi or 18 months for Ms. Corcoran, (b) any unpaid bonus earned for the year prior to the year of termination, a prorated portion of the named executive officer's target annual bonus for the year of termination and a payment equal to 2 times for Dr. Sommadossi or 1.5 times for Ms. Corcoran the named executive officer's target annual bonus for the year of termination, (c) direct payment of or reimbursement for COBRA premiums, less the amount the named executive officer would have paid for coverage as an active employee, for up to 24 months for Dr. Sommadossi or 18 months for Ms. Corcoran and (d) all unvested equity or equity-based awards that vest solely based on the named executive officer's continued employment or service with the Company will accelerate and vest in respect of 100% of the shares subject thereto.

Under the employment agreements, "cause" means, subject to notice and cure rights, a named executive officer's (i) refusal to substantially perform duties or carry out reasonable and lawful instructions concerning duties, (ii) breach of a material provision of the employment agreement, (iii) conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude, (iv) unlawful use or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing his or her duties and responsibilities under the employment agreement or (v) commission of an act of fraud, embezzlement, misappropriation, willful misconduct or breach of fiduciary duty against the Company or any of its affiliates.

[Table of Contents](#)

Under the employment agreements, “good reason” means, subject to notice and cure rights, (i) a reduction in annual base salary or target annual bonus, (ii) a material decrease in authority or areas of responsibility, (iii) the relocation of the named executive officer’s primary office to a location more than 25 miles from the named executive officer’s primary office as of the date of this offering or (iv) the Company’s breach of a material provision of the employment agreement.

Director Compensation

Historically, our non-employee directors have not received cash compensation for their services and have instead, from time to time, been compensated with stock option awards in amounts determined by our board of directors. In September 2019, at the time of his election to the board of directors, we granted Mr. Berger an option to purchase 50,000 shares of our common stock for an exercise price of \$1.43 per share, which our board of directors determined to be the per share fair market value of our common stock on the date of grant. The option vests on the last day of each calendar month following September 20, 2019, subject to Mr. Berger’s continued service on the applicable vesting date. None of our other non-employee directors received any compensation for serving on our board during 2019.

Dr. Sommadossi is a member of our board of directors but does not receive additional compensation for this service. Refer to “Executive Compensation” above for additional information regarding the compensation earned by Dr. Sommadossi in 2019.

2019 Director Compensation Table

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)(1)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Franklin Berger	—	—	33,015	—	—	—	33,015
Grigory Borisenko, Ph.D. (2)	—	—	—	—	—	—	—
Bihua Chen(2)	—	—	—	—	—	—	—
Isaac Cheng, M.D.	—	—	—	—	—	—	—
Bruno Lucidi	—	—	—	—	—	—	—
Polly A. Murphy, D.V.M.; Ph.D.	—	—	—	—	—	—	—
Bruce Polsky, M.D.	—	—	—	—	—	—	—
Frank Yu(3)	—	—	—	—	—	—	—
Evgeny Zaytsev(4)	—	—	—	—	—	—	—

(1) Amount reflects the full grant-date fair value of stock options granted during 2019 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by Mr. Berger. We provide information regarding the assumptions used to calculate the value of the option awards in Note 9 to the annual consolidated financial statements included in this prospectus.

(2) Dr. Borisenko and Ms. Chen resigned from our board of directors effective October 29, 2020.

(3) Mr. Yu resigned from our board of directors on December 11, 2019.

(4) Mr. Zaytsev resigned from our board of directors on January 31, 2019.

[Table of Contents](#)

The table below shows the aggregate numbers of option awards (exercisable and unexercisable) held as of December 31, 2019 by each non-employee director who was serving as of December 31, 2019. None of these individuals held unvested stock awards as of December 31, 2019.

Name	Options Outstanding at Fiscal Year End
Franklin Berger	50,000
Bruno Lucidi	125,000
Bruce Polsky, M.D.	125,000
Grigory Borisenko, Ph.D.(1)	—
Bihua Chen(1)	—
Isaac Cheng, M.D.	—

(1) Dr. Borisenko and Ms. Chen resigned from our board of directors effective October 29, 2020.

Effective on the effective date of the registration statement of which this prospectus is a part, we adopted and, prior to commencing this offering, our stockholders approved a compensation program for our non-employee directors under which each non-employee director will receive the following amounts for their services on our board of directors:

- an option to purchase 80,000 shares of our common stock upon the director's initial election or appointment to our board of directors that occurs after our initial public offering
- if the director has served on our board of directors for at least six months as of the date of an annual meeting of stockholders, an option to purchase 40,000 shares of our common stock on the date of the annual meeting,
- an annual director fee of \$40,000, and
- if the director serves on a committee of our board of directors or in the other capacities stated below, an additional annual fee as follows:
 - chairman of the board or lead independent director, \$15,000,
 - chairman of the audit committee, \$15,000,
 - audit committee member other than the chairman, \$7,500,
 - chairman of the compensation committee, \$12,000,
 - compensation committee member other than the chairman, \$6,000,
 - chairman of the nominating and corporate governance committee, \$8,000, and
 - nominating and corporate governance committee member other than the chairman, \$4,000.

Options granted to our non-employee directors under the program will have an exercise price equal to the fair market value of our common stock on the date of grant and will expire not later than ten years after the date of grant. The options granted upon a director's initial election or appointment will vest in thirty-six (36) substantially equal monthly installments following the date of grant. The options granted annually to directors will vest in twelve substantially equal monthly installments following the date of grant. In addition, all unvested options will vest in full upon the occurrence of a change in control.

Director fees under the program will be payable in arrears in four equal quarterly installments not later than the fifteenth day following the final day of each calendar quarter, provided that the amount of each payment

[Table of Contents](#)

will be prorated for any portion of a quarter that a director is not serving as a non-employee director on our board and no fee will be payable in respect of any period prior to the effective date of the registration statement of which this prospectus is a part.

In August 2020, in connection with Dr. Murphy's appointment, our board of directors granted Dr. Murphy an option under our Prior Plan to purchase 80,000 shares. The option has a per share exercise price of \$6.84, which our board of directors determined to be the per share fair market value of our common stock on the date of grant, and vests in 36 substantially equal monthly installments following Dr. Murphy's appointment to our board of directors.

In addition, effective on the effective date of the registration statement of which this prospectus is a part, our board of directors granted options under our 2020 Plan to purchase 80,000 shares to each of Mr. Berger, Dr. Cheng, Dr. Hack, Mr. Lucidi, Dr. Polsky and Ms. Duncan. The options have a per share exercise price equal to the initial public offering price per share of our common stock and vest in 36 substantially equal monthly installments occurring upon such individual's completion of each full month of service as a member of the board of directors following the effective date of grant, subject to full accelerated vesting upon the occurrence of a change in control.

Incentive Compensation Plans

The following summarizes the material terms of the 2020 Plan and the 2020 ESPP, which will be the long-term incentive compensation plans in which our directors and named executive officers are eligible to participate following the consummation of this offering, and the Prior Plan, under which we have previously made periodic grants of equity and equity-based awards to our directors and named executive officers.

2020 Incentive Award Plan

In October 2020, our board of directors adopted and our stockholders approved the 2020 Plan, which became effective the day prior to the first public trading date of our common stock, under which we may grant cash and equity-based incentive awards to eligible service providers in order to attract, retain and motivate the persons who make important contributions to the Company. The material terms of the 2020 Plan are summarized below.

Eligibility and Administration

Our employees, consultants and directors, and employees, directors and consultants of our subsidiaries, will be eligible to receive awards under the 2020 Plan. The 2020 Plan will be administered by our board of directors, which may delegate its duties and responsibilities to one or more committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to the limitations imposed under the 2020 Plan, Section 16 of the Exchange Act, stock exchange rules and other applicable laws. The plan administrator will have the authority to take all actions and make all determinations under the 2020 Plan, to interpret the 2020 Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2020 Plan as it deems advisable. The plan administrator will also have the authority to grant awards, determine which eligible service providers receive awards and set the terms and conditions of all awards under the 2020 Plan, including any vesting and vesting acceleration provisions, subject to the conditions and limitations in the 2020 Plan.

Shares Available for Awards

An aggregate of 7,924,000 shares of our common stock are initially available for issuance under the 2020 Plan. The number of shares initially available for issuance will be increased on January 1 of each calendar year beginning in 2020 and ending in and including 2029, equal to the lesser of (A) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) a smaller number of shares determined by our board of directors. No more than 55,468,000 shares of common stock may be issued under the 2020 Plan upon the exercise of incentive stock options, or ISOs. Shares issued under the 2020 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares.

If an award under the 2020 Plan or the Prior Plan expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2020 Plan. Awards granted under the 2020 Plan in substitution for any options or other stock or stock-based awards granted by an entity before the entity's merger or consolidation with us or our acquisition of the entity's property or stock will not reduce the shares available for grant under the 2020 Plan, but may count against the maximum number of shares that may be issued upon the exercise of ISOs.

Awards

The 2020 Plan provides for the grant of stock options, including ISOs, and nonqualified stock options, or NSOs, stock appreciation rights, or SARs, restricted stock, dividend equivalents, restricted stock units, or RSUs, and other stock or cash based awards. Certain awards under the 2020 Plan may constitute or provide for payment of "nonqualified deferred compensation" under Section 409A of the Code. All awards under the 2020 Plan will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

- **Stock Options and SARs.** Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The plan administrator will determine the number of shares covered by each option and SAR, the exercise price of each option and SAR and the conditions and limitations applicable to the exercise of each option and SAR. The exercise price of a stock option or SAR will not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute awards granted in connection with a corporate transaction. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders).
- **Restricted Stock and RSUs.** Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met, RSUs may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted stock and RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2020 Plan.

[Table of Contents](#)

- Other Stock or Cash Based Awards. Other stock or cash based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock or other property. Other stock or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled. The plan administrator will determine the terms and conditions of other stock or cash based awards, which may include any purchase price, performance goal, transfer restrictions and vesting conditions.

Performance Criteria

The plan administrator may select performance criteria for an award to establish performance goals for a performance period. Performance criteria under the 2020 Plan may include, but are not limited to, the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue, or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonuses); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including but not limited to those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals may be based solely upon the Company's performance or the performance of a subsidiary, division, business segment or business unit of the Company or a subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies. When determining performance goals, the plan administrator may provide for exclusion of the impact of an event or occurrence which the plan administrator determines should appropriately be excluded, including, without limitation, non-recurring charges or events, acquisitions or divestitures, changes in the corporate or capital structure, events unrelated to the business or outside of the control of management, foreign exchange considerations, and legal, regulatory, tax or accounting changes.

Certain Transactions

In connection with certain corporate transactions and events affecting our common stock, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2020 Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. This includes canceling awards for cash or property, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares subject to outstanding

[Table of Contents](#)

awards and/or with respect to which awards may be granted under the 2020 Plan and replacing or terminating awards under the 2020 Plan. In addition, in the event of certain non-reciprocal transactions with our stockholders, the plan administrator will make equitable adjustments to awards outstanding under the 2020 Plan as it deems appropriate to reflect the transaction.

Provisions of the 2020 Plan Relating to Director Compensation.

The 2020 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2020 Plan's limitations. Prior to commencing this offering, we intend to approve and implement a compensation program for our non-employee directors, which is described above under the heading "Director Compensation." Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation or other compensation and the grant date fair value of any equity awards granted under the 2020 Plan as compensation for services as a non-employee director during any fiscal year may not exceed \$1,000,000 in the fiscal year of the non-employee director's initial service and \$750,000 in any other fiscal year. The plan administrator may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the plan administrator may determine in its discretion, subject to the limitations in the 2020 Plan.

Plan Amendment and Termination

Our board of directors may amend or terminate the 2020 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2020 Plan, may materially and adversely affect an award outstanding under the 2020 Plan without the consent of the affected participant, and stockholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws. Further, the plan administrator may, without the approval of our stockholders, amend any outstanding stock option or SAR to reduce its price per share, other than in the context of corporate transactions or equity restructurings, as described above. The 2020 Plan will remain in effect until the tenth anniversary of its effective date, unless earlier terminated by our board of directors. No awards may be granted under the 2020 Plan after its termination.

Foreign Participants, Claw-back Provisions, Transferability and Participant Payments

The plan administrator may modify awards granted to participants who are foreign nationals or employed outside the United States or establish subplans or procedures to address differences in laws, rules, regulations or customs of such foreign jurisdictions. All awards will be subject to any Company claw-back policy as set forth in such claw-back policy or the applicable award agreement. Except as the plan administrator may determine or provide in an award agreement, awards under the 2020 Plan are generally non-transferrable, except by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2020 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2020 Plan, the plan administrator may, in its discretion, accept cash, wire transfer or check, shares of our common stock that meet specified conditions, a promissory note, a "market sell order," other consideration as the plan administrator deems suitable or any combination of the foregoing.

2020 Employee Stock Purchase Plan

In October 2020, our board of directors adopted and our stockholders approved the 2020 ESPP, which became effective the day prior to the first public trading date of our common stock and the material terms of which are summarized below.

Shares Available for Awards; Administration

A total of 1,187,000 shares of our common stock are initially reserved for issuance under the 2020 ESPP. In addition, the number of shares available for issuance under the 2020 ESPP will be annually increased on January 1 of each calendar year beginning in 2020 and ending in and including 2030, by an amount equal to the lesser of (A) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our board of directors, provided that no more than 10,696,000 shares of our common stock may be issued under the 2020 ESPP. Our board of directors or a committee of our board of directors will administer and will have authority to interpret the terms of the 2020 ESPP and determine eligibility of participants. We expect that the compensation committee of our board of directors will be the initial administrator of the 2020 ESPP.

Eligibility

All of our employees are eligible to participate in the 2020 ESPP. However, an employee may not be granted rights to purchase stock under our 2020 ESPP if the employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our stock.

Grant of Rights

The 2020 ESPP is intended to qualify under Section 423 of the Code and stock will be offered under the 2020 ESPP during offering periods. The length of the offering periods under the 2020 ESPP will be determined by the plan administrator and may be up to twenty-seven months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in the offering period. Offering periods under the 2020 ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The 2020 ESPP permits participants to purchase common stock through payroll deductions of up to a specified percentage of their eligible compensation. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period. In addition, no employee will be permitted to accrue the right to purchase stock under the 2020 ESPP at a rate in excess of \$25,000 worth of shares during any calendar year during which a purchase right under the 2020 ESPP is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will expire at the end of the applicable offering period, and will be exercised at that time to the extent of the payroll deductions accumulated during the offering period. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the purchase date. Participants may voluntarily end their participation in the 2020 ESPP at any time during a specified period prior to the end of the applicable offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

[Table of Contents](#)

A participant may not transfer rights granted under the 2020 ESPP, other than by will or the laws of descent and distribution. A participant's rights under the 2020 ESPP are generally exercisable only by the participant.

Certain Transactions

In the event of certain non-reciprocal transactions or events affecting our common stock, the plan administrator will make equitable adjustments to the 2020 ESPP and outstanding rights. In the event of certain unusual or non-recurring events or transactions, including a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or the termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or the parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares of stock subject to outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and the termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights.

Plan Amendment

The plan administrator may amend, suspend or terminate the 2020 ESPP at any time. However, stockholder approval will be obtained for any amendment that increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the 2020 ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the 2020 ESPP or changes the 2020 ESPP in any manner that would cause the 2020 ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code.

2013 Equity Incentive Plan

Our board of directors and stockholders have approved our Prior Plan, under which we may grant stock options and other stock-based awards to employees, directors and consultants of the Company. We have reserved a total of 10,979,971 shares of our common stock for issuance under the Prior Plan.

Following the effectiveness of the 2020 Plan, we will not make any further grants under the Prior Plan. However, the Prior Plan will continue to govern the terms and conditions of the outstanding awards granted under it. Shares of our common stock subject to awards granted under the Prior Plan that are forfeited, lapse unexercised or are settled in cash and which following the effective date of the 2020 Plan are not issued under the Prior Plan will be available for issuance under the 2020 Plan.

Eligibility and Administration

Our employees, officers, and directors, as well as consultants and advisors to the Company are eligible to receive awards under the Prior Plan. Our board of directors or a committee thereof administers the Prior Plan. Subject to the express terms and conditions of the Prior Plan, the plan administrator has the authority to make all determinations and interpretations under the Prior Plan, prescribe all forms for use with the Prior Plan and adopt, alter and/or rescind rules, guidance and practices for the administration of the Prior Plan. The plan administrator also sets the terms and conditions of all awards under the Prior Plan, including any vesting and vesting acceleration conditions.

Awards

The Prior Plan provides for the grant of stock options (including NSOs and ISOs), restricted stock, RSUs, and other equity-based awards. As of September 30, 2020, options to purchase 7,001,747 shares of our common stock and 200,000 shares of restricted stock were outstanding under the Prior Plan.

Certain Transactions

The plan administrator has broad discretion to adjust the provisions of the Prior Plan and the terms and conditions of awards, including with respect to aggregate number and kind of shares subject to the Prior Plan and awards granted pursuant to the Prior Plan and the purchase or exercise price of awards granted pursuant to the Prior Plan, to prevent substantial dilution or enlargement of the rights of participants under the Prior Plan in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, recapitalizations, consolidations and other corporate transactions. The plan administrator may also provide for the acceleration, cash-out, assumption, substitution or conversion of awards in the event of a certain transactions, including a “change in control” (as such term is defined in the Prior Plan).

Amendment and Termination

The plan administrator may terminate, amend or modify the Prior Plan at any time and from time to time. The administrator may also amend, modify or terminate any outstanding award, including but not limited to, substituting therefor another award. No change to the Prior Plan or an award outstanding under the Prior Plan may materially and adversely affect outstanding awards without the holder’s consent. Furthermore, we must generally obtain stockholder approval to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule).

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2017 to which we have been a party in which the amount involved exceeded or will exceed \$120,000 and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Preferred Stock Financings

Series C Preferred Stock Financing. From June 2018 to July 2018, we issued and sold to investors in private placements an aggregate of 6,052,617 shares of our Series C convertible preferred stock at a purchase price of \$4.56 per share, for aggregate consideration of approximately \$27.6 million.

Series D Preferred Stock Financing. In May 2020, we issued and sold to investors in a private placement an aggregate of 15,313,382 shares of our Series D convertible preferred stock at a purchase price of \$7.02 per share, for aggregate consideration of approximately \$107.5 million.

Series D-1 Preferred Stock Financing. In October 2020, we issued and sold to investors in a private placement an aggregate of 8,973,261 shares of our Series D-1 convertible preferred stock at a purchase price of \$11.98 per share, for aggregate consideration of approximately \$107.5 million.

The following table sets forth the aggregate number of shares of our capital stock acquired by beneficial owners of more than 5% of our capital stock in the financing transactions described above. Each share of our Series C preferred stock identified in the following table will convert into one share of common stock immediately prior to the closing of this offering. Each share of our Series D preferred stock identified in the following table will convert into one share of common stock immediately prior to the closing of this offering.

Participants	Series C Preferred Stock	Series D Preferred Stock	Series D-1 Preferred Stock
5% or Greater Stockholders⁽¹⁾			
Bain Capital Life Sciences Fund II, L.P.	—	3,015,872	1,767,230
BCIP Life Sciences Associates, LP	—	367,318	215,239
Cormorant Private Healthcare Fund I, LP	1,951,053	—	—
Cormorant Private Healthcare Fund II L.P.	—	575,427	337,185
Cormorant Global Healthcare Master Fund, LP	587,632	136,823	80,175
Morningside Venture Investments Limited	800,438	1,068,376	626,043

(1) Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption "Principal Stockholders."

Some of our directors and former directors are associated with our principal stockholders as indicated in the table below:

Director	Principal Stockholder
Bihua Chen	Cormorant Private Healthcare Fund I, LP Cormorant Private Healthcare Fund II L.P. Cormorant Global Healthcare Master Fund, LP
Andrew Hack, M.D. Ph.D.	Bain Capital Life Sciences Fund II, L.P. BCIP Life Sciences Associates, LP
Isaac Cheng, M.D.	Morningside Venture Investments Limited

Stockholders Agreement

We entered into a Fourth Amended and Restated Stockholders Agreement on May 19, 2020, by and among us and certain of our stockholders, pursuant to which the following directors or former directors were designated to serve as members on our board of directors: Dr. Sommadossi, Mr. Berger, Dr. Borisenko, Ms. Chen, Dr. Cheng, Dr. Hack, Mr. Lucidi, Dr. Murphy and Dr. Polsky. Dr. Jean-Pierre Sommadossi, Mr. Franklin Berger, Dr. Bruce Polsky and Mr. Bruno Lucidi were selected to serve on our board of directors as a representatives of holders of our common stock. Dr. Cheng was selected to serve on our board of directors as a representative of holders of our Series A preferred stock. Dr. Borisenko was selected to serve on our board of directors as a representative of holders of our preferred stock, as designated by the entities affiliated with RMI Investments S.A.R.L. Ms. Chen was selected to serve on our board of directors as a representative of holders of our preferred stock, as designated by the entities affiliated with Cormorant Private Healthcare Fund I, LP. Dr. Hack was selected to serve on our board of directors as a representative of holders of our preferred stock, as designated by the entities affiliated with Bain Capital Life Sciences Investors, LLC.

The stockholders agreement will terminate upon the consummation of this offering. The composition of our board of directors after this offering is described in more detail under “Management—Board Composition and Election of Directors.”

Indemnification Agreements

We intend to enter into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer. For further information, see “Executive and Director Compensation—Limitations of Liability and Indemnification.”

Stock Option Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain of our directors as more fully described in the section entitled “Executive and Director Compensation.”

Danforth Consulting Agreement

In August 2019, we engaged Danforth, a consulting firm specializing in providing financial and strategic support to life sciences companies and an affiliate of Daniel Geffken, who served as our interim Chief Financial Officer from August 2019 to October 2020. On October 1, 2020 we notified Danforth that we are terminating this agreement, which will terminate 60 days from the date of notification. Pursuant to this agreement, we paid professional fees to Danforth of \$145,000 and granted stock options to purchase 116,891 shares of common stock at an exercise price of \$1.43 per share to Mr. Geffken in 2019. See “Executive and Director Compensation—Executive Compensation Arrangements.”

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related

[Table of Contents](#)

person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds \$120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock, as of September 30, 2020 by:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the Securities and Exchange Commission. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on 68,241,937 shares of common stock outstanding as of September 30, 2020, assuming the conversion of all outstanding shares of preferred stock into common stock and after giving effect to the Series D-1 Closing. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of September 30, 2020 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 125 Summer Street, Boston, MA 02110. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares of Common Stock	Percentage Before this Offering	Percentage After this Offering
5% or Greater Stockholders			
Morningside Investments Limited(1)	6,484,956	9.50%	8.03%
Entities Affiliated with Cormorant Private Healthcare Fund I, LP(2)	6,411,355	9.40%	7.94%
JPM Partners LLC(3)	5,925,000	8.68%	7.34%
Entities Affiliated with Bain Capital Life Sciences Investors, LLC(4)	5,365,659	7.86%	6.65%
Entities Affiliated with ABG-ATEAB LIMITED(5)	3,842,866	5.63%	4.76%
Named Executive Officers and Directors			
Jean-Pierre Sommadossi, Ph.D.(3)(6)	6,754,443	9.78%	8.28%
Andrea Corcoran(7)	806,337	1.18%	1.00%
Daniel Geffken(8)	73,056	*	*
Franklin Berger(9)	788,772	1.16%	*
Isaac Cheng, M.D.	—	—	—
Barbara Duncan	—	—	—
Andrew Hack, M.D., Ph.D.(10)	—	—	—
Bruno Lucidi(11)	172,916	*	*
Polly A. Murphy, D.V.M., Ph.D.(12)	17,961	*	*
Bruce Polsky, M.D.(13)	172,916	*	*
All executive officers and directors as a group (13 persons)(14)	9,003,698	13.07%	11.06%

Table of Contents

- * Less than 1%.
- (1) Consists of 6,484,956 shares of common stock issuable upon conversion of shares of convertible preferred stock held by Morningside Venture Investments Limited ("Morningside"). Raymond Long Sing Tang, Frances Anne Elizabeth Richard, Peter Stuart Allenby Edwards and Jill Marie Franklin are directors of Morningside, and may be deemed to have joint voting and dispositive power with respect to the shares held by Morningside. Each of Mr. Tang, Ms. Richard, Mr. Edwards and Ms. Franklin disclaim beneficial ownership of the shares held by Morningside, except to the extent of his or her pecuniary interest therein, if any. The address of Morningside is 2nd Floor, Le Prince de Galles, 3-5 Avenue Citronniers, MC 98000, Monaco.
 - (2) Consists of (i) 3,106,168 shares of common stock issuable upon conversion of shares of convertible preferred stock held by Cormorant Private Healthcare Fund I, LP (Cormorant Fund I), (ii) 912,612 shares of common stock issuable upon conversion of shares of convertible preferred stock held by Cormorant Private Healthcare Fund II, LP ("Cormorant Fund II"), (iii) 2,043,170 shares of common stock issuable upon conversion of shares of convertible preferred stock held by Cormorant Global Healthcare Master Fund, LP ("Cormorant Master Fund") and (iv) 349,405 shares issuable upon conversion of shares of convertible preferred stock held by CRMA SPV, L.P. ("CRMA", and together with Cormorant Fund II and Cormorant Master Fund, the "Cormorant Funds"). Cormorant Global Healthcare GP, LLC ("Global GP") is the general partner of Cormorant Master Fund and Cormorant Private Healthcare 11 GP, LLC ("Private GP") is the general partner of Cormorant II. Bihua Chen serves as the managing member of both Global GP and Private GP. Cormorant Asset Management LP serves as the investment manager to Cormorant Fund II, Cormorant Master Fund and CRMA, and Ms. Chen serves as the managing member of Cormorant Asset Management GP, LLC. Ms. Chen has sole voting and investment control over the shares held by the Cormorant Funds. Ms. Chen disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein. The address of the Cormorant Funds, Global GP, Private GP, Cormorant Asset Management LP, and Ms. Chen is 200 Clarendon Street, 52nd Floor, Boston, Massachusetts 02116.
 - (3) Consists of 5,175,000 shares of common stock and 750,000 shares of common stock issuable upon conversion of shares of convertible preferred stock held by JPM Partners LLC, of which Jean-Pierre Sommadossi, Ph.D. is the manager and may be deemed to have sole voting and dispositive power with respect to such shares.
 - (4) Consists of (i) 4,783,102 shares of common stock issuable upon conversion of shares of convertible preferred stock held by Bain Capital Life Sciences Fund II, L.P. ("BC LS") and (ii) 582,557 shares of common stock issuable upon conversion of shares of convertible preferred stock held by BCIP Life Sciences Associates, LP ("BCIP LS" and, together with BC LS, the "Bain Capital Life Sciences Entities"). Bain Capital Life Sciences Investors, LLC, whose managers are Jeffrey Schwartz and Adam Koppel, is the manager of the general partner of BC LS and governs the investment strategy and decision-making process with respect to investments held by BCIP LS. As a result, each of Bain Capital Life Sciences Investors, LLC, Mr. Schwartz and Dr. Koppel may be deemed to share voting and dispositive power over the shares held by the Bain Capital Life Sciences Entities. The address of the Bain Capital Life Sciences Entities is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, MA 02116.
 - (5) Consists of (i) 2,639,178 shares of common stock issuable upon conversion of shares of convertible preferred stock held by ABG-ATEAB Limited ("ABG-ATEAB"), (ii) 300,000 shares of common stock issuable upon conversion of shares of convertible preferred stock held by ABG-ATEA Limited ("ABG-ATEA"), and (iii) 903,688 shares of common stock issuable upon conversion of shares of convertible preferred stock held by Ally Bridge MedAlpha Master Fund L.P. ("MedAlpha"). ABG-ATEAB is a wholly-owned subsidiary of Ally Bridge Group Innovation Capital Partners III, L.P. ("ABG III"). ABG Innovation Capital Partners III GP Limited ("ABG III GP") is the general partner of ABG Innovation Capital Partners III GP, L.P. (together with ABG III and ABG III GP, the "ABG III Entities"), which is the general partner of ABG III. Mr. Fan Yu is the sole shareholder and a director of ABG III GP and as such, Mr. Fan Yu and each of the ABG III Entities may be deemed to share beneficial ownership of the shares held of record by ABG-ATEAB. ABG-ATEA is a wholly-owned subsidiary of Ally Bridge Group ("ABG"). Ally Bridge Group (HK) Limited ("ABG HK") is ABG I's investment manager. Mr. Fan Yu, a director of ABG I and ABG HK, owns the entire management share of ABG I and indirectly controls all equity interest in ABG HK and as such, Mr. Fan Yu and each of ABG I and ABG HK may be deemed to share beneficial ownership of the shares held of record by ABG-ATEA. With respect to MedAlpha, Mr. Fan Yu indirectly controls each of Ally Bridge MedAlpha Management GP, LLC and Ally Bridge Group (NY) LLC. Ally Bridge Group (NY) LLC and Ally Bridge MedAlpha Management L.P. acting through its general partner Ally Bridge MedAlpha Management GP, LLC manage MedAlpha's investments, and as such, each of the foregoing entities and Mr. Fan Yu may be deemed to share beneficial ownership of the shares of common stock held of record by MedAlpha. Each of the entities disclaims any such beneficial ownership described in this footnote. The address of ABG-ATEA and ABG-ATEAB is Unit 3002-3004, 30th Floor, Gloucester Tower, The Landmark, No. 15 Queen's Road, Central Hong Kong. The address of MedAlpha is 430 Park Avenue, Fl 12, New York, New York 10022.
 - (6) Consists of 829,443 shares of common stock which Dr. Sommadossi has the right to acquire pursuant to outstanding share options, including options that will be exercisable within 60 days of September 30, 2020.
 - (7) Includes (i) 500,000 shares of common stock and (ii) 173,333 shares of common stock which Ms. Corcoran has the right to acquire pursuant to outstanding share options, including options that will be exercisable within 60 days of September 30, 2020.
 - (8) Consists of 73,056 shares of common stock which Mr. Geffken has the right to acquire pursuant to outstanding share options, including options that will be exercisable within 60 days of September 30, 2020.
 - (9) Includes (i) 18,747 shares of common stock and (ii) 10,419 shares of common stock which Mr. Berger has the right to acquire pursuant to outstanding share options, including options that will be exercisable within 60 days of September 30, 2020.
 - (10) Does not include shares of common stock issuable upon conversion of shares of convertible preferred stock held by the Bain Capital Life Sciences Entities. Dr. Hack is a Managing Director of Bain Capital Life Sciences Investors, LLC. As a result, by virtue of the relationships described in footnote 4 above, Dr. Hack may be deemed to share beneficial ownership of such securities held by the Bain Capital Life Sciences Entities. The address of Dr. Hack is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, Massachusetts 02116.
 - (11) Includes (i) 50,000 shares of common stock and (ii) 122,916 shares of common stock which Mr. Lucidi has the right to acquire pursuant to outstanding share options, including options that will be exercisable within 60 days of September 30, 2020.
 - (12) Includes (i) 11,295 shares of common stock issuable upon conversion of shares of convertible preferred stock held by the Marc & Polly Murphy Revocable Family Trust dated March 13, 2002, of which Dr. Murphy has voting and dispositive control and (ii) 6,666 shares of common stock which Dr. Murphy has the right to acquire pursuant to outstanding share options, including options that will be exercisable within 60 days of September 30, 2020.

Table of Contents

- (13) Includes (i) 50,000 shares of common stock and (ii) 122,916 shares of common stock which Dr. Polsky has the right to acquire pursuant to outstanding share options, including options that will be exercisable within 60 days of September 30, 2020.
- (14) Includes (i) 5,793,747 shares of common stock (ii) 1,736,413 shares of common stock issuable upon conversion of convertible preferred stock, and (iii) 1,473,538 shares of common stock which the executive officers and directors have the right to acquire pursuant to outstanding share options, including options that will be exercisable within 60 days of September 30, 2020.

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes some of the terms of our restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering, the investors' rights agreement and of the General Corporation Law of the State of Delaware. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our restated certificate of incorporation, amended and restated bylaws and investors' rights agreement, copies of which have been or will be filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the General Corporation Law of the State of Delaware. The description of our common stock and preferred stock reflects changes to our capital structure that will occur immediately prior the closing of this offering.

Following the closing of this offering, our authorized capital stock will consist of 300,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share.

As of September 30, 2020, there were 10,309,847 shares of our common stock outstanding held of record by 31 stockholders, including 200,000 shares of unvested restricted common stock subject to repurchase by us, 20,000,000 shares of Series A Preferred Stock held of record by 61 stockholders, 7,592,830 shares of Series B Preferred Stock held of record by 34 stockholders, 6,052,617 shares of Series C Preferred Stock held of record by 38 stockholders, 15,313,382 shares of Series D Preferred Stock held of record by 38 stockholders, and no shares of Series D-1 Preferred Stock held of record by any stockholders.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our restated certificate of incorporation. See below under "—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Charter Provisions." Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our restated certificate of incorporation that will become effective upon the closing of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Options

As of September 30, 2020, options to purchase 7,001,747 shares of our common stock were outstanding under our Prior Plan, of which 2,857,918 were exercisable and of which 4,143,829 were unvested as of that date.

Registration Rights

Holders of 57,932,090 shares of our common stock are entitled to certain rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to an amended and restated stockholders rights agreement by and among us and certain of our stockholders, until the rights otherwise terminate pursuant to the terms of the investors' rights agreement. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Form S-1 Registration Rights

If at any time beginning 180 days after the closing date of this offering the holders of a majority of registrable securities request in writing that we effect a registration with respect to all or part of such registrable securities then outstanding and having an anticipated gross aggregate offering price that would exceed \$15,000,000, we may be required to register their shares; provided, however, that we will not be required to effect such a registration if, within any twelve month period, we have already effected two registrations on Form S-1 for the holders of registrable securities. If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

Piggyback Registration Rights

If at any time after this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

[Table of Contents](#)

Form S-3 Registration Rights

If, at any time after we become entitled under the Securities Act to register our shares on a registration statement on Form S-3, the holders of at least 30% of the then outstanding registrable securities request in writing that we effect a registration with respect to registrable securities at an aggregate price to the public in the offering of at least \$5,000,000, we will be required to effect such registration; provided, however, that we will not be required to effect such a registration if, within any twelve month period, we have already effected two registrations on Form S-3 for the holders of registrable securities.

Expenses and Indemnification

Ordinarily, other than underwriting discounts and commissions and subject to certain exceptions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements, not to exceed \$20,000, of a counsel for the selling security holders and blue sky fees and expenses. Additionally, we have agreed to indemnify selling stockholders for damages, and any legal or other expenses reasonably incurred, arising from or based upon any untrue statement of a material fact contained in any registration statement, an omission or alleged omission to state a material fact in any registration statement or necessary to make the statements therein not misleading, or any violation or alleged violation by the indemnifying party of securities laws, subject to certain exceptions.

Termination of Registration Rights

The registration rights terminate upon the earliest to occur of three years after the effective date of the registration statement of which this prospectus is a part, the closing of a deemed liquidation event, or such time as an exemption under the Securities Act is available for the sale of all of the registrable securities..

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see "Management—Board Composition and Election of Directors." This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine; provided that the exclusive forum provisions will not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act, or to any claim for which the federal courts have exclusive jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Act, Exchange Act, or the rules and regulations thereunder. Our restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon.

The provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC.

Stock Exchange Listing

We have been approved to have our common stock listed on The Nasdaq Global Select Market under the symbol "AVIR."

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of 80,741,937 shares of common stock, assuming the issuance of 12,500,000 shares of common stock offered by us in this offering, the automatic conversion of all outstanding shares of our preferred stock into 57,932,090 shares of our common stock and no exercise of options after September 30, 2020. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our “affiliates,” as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining 68,241,937 shares of common stock will be “restricted securities,” as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that 80,741,937 shares will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

In addition, of the 7,001,747 shares of our common stock that were subject to stock options outstanding as of September 30, 2020, options to purchase 2,857,918 shares of common stock were vested as of September 30, 2020 and, upon exercise, these shares will be eligible for sale subject to the lock-up agreements described below and Rules 144 and 701 under the Securities Act.

Lock-Up Agreements

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, have agreed that, without the prior written consent of J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Evercore Group L.L.C. and William Blair & Company, L.L.C., we and they will not, subject to certain exceptions, during the period ending 180 days after the date of this prospectus, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock; or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock, whether any transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise.

Upon the expiration of the applicable lock-up periods, all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. For a further description of these lock-up agreements, please see “Underwriting.”

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale,

[Table of Contents](#)

who has beneficially owned shares of our common stock for at least six months would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 807,419 shares immediately after this offering; or
- the average weekly trading volume in our common stock on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission and Nasdaq concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer’s employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

Registration Rights

Upon the closing of this offering, the holders of 57,932,090 shares of common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our preferred stock upon the closing of this offering, or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement described above.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of the shares of common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or foreign tax laws are not discussed. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or IRS, in each case in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a non-U.S. holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

This discussion is limited to non-U.S. holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a non-U.S. holder’s particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to holders subject to particular rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons for whom our common stock constitutes “qualified small business stock” within the meaning of Section 1202 of the Code;
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the stock being taken into account in an applicable financial statement. and
- tax-qualified retirement plans.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of

the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a “non-U.S. holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more United States persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has made a valid election under applicable Treasury Regulations to continue to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section in this prospectus titled “Dividend Policy,” we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “—Sale or Other Taxable Disposition of Common Stock.”

Subject to the discussion below on effectively connected income, dividends paid to a non-U.S. holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the non-U.S. holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A non-U.S. holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment or fixed base in the United States to which such dividends are attributable),

[Table of Contents](#)

the non-U.S. holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the non-U.S. holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to United States persons. A non-U.S. holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules. ***Sale or Other Taxable Disposition of Common Stock***

A non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment or fixed base in the United States to which such gain is attributable);
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests, if any, however, there can be no assurance we are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a non-U.S. holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the non-U.S. holder's holding period.

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and

[Table of Contents](#)

the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the non-U.S. holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

In addition, the proceeds of a sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person or such holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends paid on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers (and withholding agents) generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Evercore Group L.L.C. and William Blair & Company, L.L.C. are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the representatives. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of Shares
J.P. Morgan Securities LLC	4,062,500
Morgan Stanley & Co. LLC	3,750,000
Evercore Group L.L.C.	3,125,000
William Blair & Company, L.L.C.	1,562,500
Total	12,500,000

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$1.008 per share. After the initial offering of the shares to the public, if all of the common shares are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 1,875,000 additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is \$1.68 per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	\$ 1.68	\$ 1.68
Total	\$ 21,000,000	\$ 24,150,000

[Table of Contents](#)

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$3.2 million. We have agreed to reimburse the underwriters for expenses of up to \$50,000 related to clearance of this offering with the Financial Industry Regulatory Authority, or FINRA.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, loan, disposition or filing, or (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Evercore Group L.L.C. and William Blair & Company, L.L.C. for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to (i) the issuance of shares of common stock or securities convertible into or exercisable for shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of restricted stock units ("RSU") (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise of stock options or otherwise) to our employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing of this offering and described in this prospectus; (iii) the issuance of up to 5% of the outstanding shares of our common stock, or securities convertible into, exercisable for, or which are otherwise exchangeable for, our common stock, immediately following the closing of this offering, in acquisitions or other similar strategic transactions; or (iv) our filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any plan in effect on the date of the underwriting agreement and described in this prospectus or any assumed benefit plan pursuant to an acquisition or similar strategic transaction; provided that the recipient of any such shares or securities issued or granted pursuant to clauses (i), (ii) and (iii) during the 180-day restriction period described above shall enter into a "lock-up" agreement with the underwriters.

Our directors, executive officers and our shareholders (such persons, the "lock-up parties") have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the "restricted period"), may not (and may not cause any of their direct or indirect affiliates to), without the prior written consent of J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Evercore Group L.L.C. and William Blair & Company, L.L.C., (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into

Table of Contents

or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a stock option or warrant) (collectively with the common stock, the “lock-up securities”), (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of lock-up securities, in cash or otherwise, (3) make any demand for, or exercise any right with respect to, the registration of any lock-up securities, or (4) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged and agreed that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such agreement) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) transfers of lock-up securities: (i) as bona fide gifts, or for bona fide estate planning purposes, (ii) by will or intestacy, (iii) to any trust for the direct or indirect benefit of the lock-up party or any immediate family member, or if the lock-up party is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust, (iv) to a partnership, limited liability company or other entity of which are controlled or managed by the lock-up party or its immediate family members or under common control of the lock-up party, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv), (vi) in the case of a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or its affiliates or (B) as part of a distribution to members or stockholders of the lock-up party; (vii) by operation of law, (viii) to us from an employee upon death, disability or termination of employment of such employee, (ix) as part of a sale of lock-up securities acquired in this offering or in open market transactions after the completion of this offering, (x) to us in connection with the vesting, settlement, or exercise of restricted stock units, options, warrants or other rights to purchase shares of our common stock (including “net” or “cashless” exercise), including for the payment of exercise price and tax and remittance payments, provided that any such shares of common stock received upon such exercise, vesting or settlement shall be subject to a similar lock-up agreement with the underwriters, and provided further that any such restricted stock units, options, warrants or rights are held by the lock-up parties pursuant to an agreement or equity awards granted under a stock incentive plan or other equity award plan, each such agreement or plan which is described herein, or (xi) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction approved by our board of directors and made to all shareholders involving a change in control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph; (b) exercise of the options, settlement of RSUs or other equity awards, or the exercise of warrants granted pursuant to plans described in this prospectus, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to a similar lock-up agreement with the underwriters; (c) the conversion of outstanding preferred stock, warrants to acquire preferred stock, or convertible securities into shares of our common stock or warrants to acquire shares of our common stock,

[Table of Contents](#)

provided that any common stock or warrant received upon such conversion would be subject to a similar lock-up agreement with the underwriters; and (d) the establishment by lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act, provided that (i) such plan does not provide for the transfer of lock-up securities during the restricted period and (ii) no filing by any party under the Exchange Act or other public announcement shall be required or made voluntarily in connection with such trading plan;

provided that (A) in the case of any transfer or distribution pursuant to clause (a)(i), (ii), (iii), (iv), (v), (vi) and (vii), such transfer shall not involve a disposition for value and each donee, devisee, transferee or distributee shall enter into a similar lock-up agreement with the underwriters and (B) in the case of any transfer or distribution pursuant to clause (a) (i), (ii), (iii), (iv), (v), (vi), (ix) and (x), no filing by any party (donor, donee, devisee, transferor, transferee, distributor or distributee) under the Exchange Act, or other public announcement shall be required or shall be made voluntarily in connection with such transfer or distribution (other than a filing on a Form 5 made after the expiration of the restricted period). J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Evercore Group L.L.C. and William Blair & Company, L.L.C., in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Our common stock has been approved for listing/quotation on The Nasdaq Global Select Market under the symbol "AVIR."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on The Nasdaq Global Select Market, in the over-the-counter market or otherwise.

[Table of Contents](#)

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering; and
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the shares will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Other Activities and Relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. William Blair & Company, L.L.C. provided certain financial advisory and investment banking services in connection with our Series D closings and Evercore Group L.L.C. served as our financial advisor in connection with the Roche License Agreement. Evercore Group L.L.C. received customary fees and expenses in connection with this role. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Selling Restrictions

Notice to prospective investors in European Economic Area and United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation,

[Table of Contents](#)

except that it may make an offer to the public in that Relevant State of any shares at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

Notice to prospective investors in United Kingdom

In the United Kingdom, this prospectus supplement is only being distributed to, and is only directed at, and any investment or investment activity to which this prospectus supplement relates is available only to, and will be engaged in only with, persons who are “qualified investors” (as defined in the Prospectus Regulation) (i) having professional experience in matters relating to investments who fall within the definition of “investment professionals” in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “Order”); or (ii) who are high net worth entities falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). Persons who are not relevant persons should not take any action on the basis of this prospectus supplement and should not act or rely on it.

Notice to prospective investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (“CISA”). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to prospective investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to prospective investors in Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the “Corporations Act”);
- has not been, and will not be, lodged with the Australian Securities and Investments Commission (“ASIC”), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act (“Exempt Investors”).

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in

[Table of Contents](#)

section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to prospective investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to prospective investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the "SFO") of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) (the "CO") or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

Notice to prospective investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the "SFA")) pursuant to Section 274 of the SFA; (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

[Table of Contents](#)

securities or securities-based derivatives contract (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Singapore SFA Product Classification—Solely for the purposes of its obligations pursuant to sections 309B(1)(a) and 309B(1)(c) of the SFA, the Company has determined, and hereby notifies all relevant persons (as defined in Section 309A of the SFA) that the shares are “prescribed capital markets products” (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP. Certain legal matters will be passed upon for the underwriters by Davis Polk & Wardwell LLP.

EXPERTS

The consolidated financial statements of Atea Pharmaceuticals, Inc. as of December 31, 2019 and 2018, and for the years then ended, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon completion of this offering, we will be required to file periodic reports, proxy statements, and other information with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934. The Securities and Exchange Commission maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the Securities and Exchange Commission. The address of that site is www.sec.gov.

ATEA PHARMACEUTICALS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Years ended December 31, 2019 and 2018	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations and Comprehensive Loss	F-4
Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7
Interim financial statements (Unaudited)	
Consolidated Balance Sheets	F-24
Consolidated Statements of Operations and Comprehensive Loss	F-25
Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit	F-26
Consolidated Statements of Cash Flows	F-27
Notes to Consolidated Financial Statements	F-28

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Atea Pharmaceuticals, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Atea Pharmaceuticals, Inc. and subsidiary (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2014.

Boston, Massachusetts

June 18, 2020

ATEA PHARMACEUTICALS, INC.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	December 31,	
	2019	2018
Assets		
Current assets		
Cash and cash equivalents	\$ 21,661	\$ 34,492
Prepaid expenses and other current assets	249	206
Total current assets	21,910	34,698
Property and equipment, net	41	56
Other assets	122	107
Total assets	\$ 22,073	\$ 34,861
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities		
Accounts payable	\$ 548	\$ 391
Accrued expenses and other current liabilities	1,887	1,369
Total current liabilities	2,435	1,760
Other liabilities	95	148
Total liabilities	2,530	1,908
Commitments and contingencies (see Note 6)		
Convertible preferred stock, \$0.001 par value; 33,645,447 shares authorized, issued and outstanding as of December 31, 2019 and 2018; liquidation preference of \$70,606 as of December 31, 2019	69,114	69,114
Stockholders' deficit:		
Common stock, \$0.001 par value; 53,070,161 shares authorized as of December 31, 2019 and 2018; 10,091,100 shares issued and outstanding as of December 31, 2019 and 2018	10	10
Additional paid-in capital	4,632	4,008
Accumulated deficit	(54,213)	(40,179)
Total stockholders' deficit	(49,571)	(36,161)
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 22,073	\$ 34,861

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

ATEA PHARMACEUTICALS, INC.**Consolidated Statements of Operations and Comprehensive Loss**

(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2019	2018
Operating expenses		
Research and development	\$ 10,170	\$ 6,675
General and administrative	4,438	2,802
Total operating expenses	14,608	9,477
Loss from operations	(14,608)	(9,477)
Interest income and other, net	574	413
Net loss and comprehensive loss	\$ (14,034)	\$ (9,064)
Net loss per share attributable to common stockholders—basic and diluted	\$ (1.39)	\$ (0.90)
Weighted-average common shares outstanding—basic and diluted	10,091,100	10,039,392
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)	\$ (0.32)	
Pro forma weighted-average common shares outstanding—basic and diluted (unaudited)	43,736,547	

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

ATEA PHARMACEUTICALS, INC.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit

(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Stockholders' Deficit
Balance—January 1, 2018	27,592,830	\$ 41,755	9,987,767	\$ 10	\$ 3,594	\$ (31,115)	\$ (27,511)
Issuance of Series C convertible preferred stock, net of issuance costs of \$241	6,052,617	27,359	—	—	—	—	—
Vesting of restricted common stock	—	—	103,333	—	—	—	—
Stock-based compensation expense	—	—	—	—	414	—	414
Net loss	—	—	—	—	—	(9,064)	(9,064)
Balance—December 31, 2018	33,645,447	69,114	10,091,100	10	4,008	(40,179)	(36,161)
Stock-based compensation expense	—	—	—	—	624	—	624
Net loss	—	—	—	—	—	(14,034)	(14,034)
Balance—December 31, 2019	33,645,447	\$ 69,114	10,091,100	\$ 10	\$ 4,632	\$ (54,213)	\$ (49,571)

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

ATEA PHARMACEUTICALS, INC.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (14,034)	\$ (9,064)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	624	414
Depreciation and amortization expense	17	17
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(43)	86
Accounts payable	157	(90)
Accrued expenses and other liabilities	465	729
Net cash used in operating activities	(12,814)	(7,908)
Cash flows from investing activities		
Additions to property and equipment	(2)	(12)
Net cash used in investing activities	(2)	(12)
Cash flows from financing activities		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	27,359
Proceeds from grant of restricted common stock award	—	124
Payments made for initial public offering costs	(15)	—
Net cash provided by (used in) financing activities	(15)	27,483
Net increase (decrease) in cash, cash equivalents and restricted cash	(12,831)	19,563
Cash, cash equivalents and restricted cash at the beginning of period	34,599	15,036
Cash, cash equivalents and restricted cash at the end of period	\$ 21,768	\$ 34,599
Cash, cash equivalents and restricted cash at the end of period		
Cash and cash equivalents	\$ 21,661	\$ 34,492
Restricted cash	107	107
Total cash, cash equivalents and restricted cash	\$ 21,768	\$ 34,599

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

ATEA PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements

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

1. Nature of Organization

Organization

Atea Pharmaceuticals, Inc. (together with its subsidiary, "Atea" or "the Company"), is a biopharmaceutical company that was incorporated in July 2012 and began principal operations in March 2014. The Company is using a chemistry driven approach and its drug discovery and development capabilities to identify and develop novel antiviral therapeutics. The Company is located in Boston, Massachusetts. Atea Pharmaceuticals Securities Corporation, or Atea PSC, a Massachusetts corporation incorporated in 2016, is a wholly owned subsidiary of Atea.

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. 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 our 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 has financed its operations to date from the sale of convertible preferred stock. Since its inception, the Company has incurred recurring operating losses and negative cash flows from operations. As of December 31, 2019, the Company had an accumulated deficit of \$54,213. The Company expects to continue to generate operating losses for the foreseeable future. As discussed in Note 13, in May 2020, the Company entered into a stock purchase agreement and issued 15,313,382 shares of Series D convertible preferred stock ("Series D Preferred") for gross proceeds of \$107,500. Management believes its existing cash resources, including \$107,500 received in May 2020, will be sufficient to fund its operations as currently planned for at least twelve months following the issuance of these financial statements.

The Company is seeking to complete an initial public offering, or IPO, of its common stock. In the event that the Company does not complete an IPO, the Company may seek additional capital through one or more of a combination of private financing through the sale of additional equity securities, debt financing or funding in connection with any 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.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP.

The preparation of 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 accrued research and development expenses and the valuation of common stock in connection with the issuance of stock-based awards. Changes in estimates are recorded in the period in which they become known.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and Atea PSC. All intercompany amounts have been eliminated in consolidation.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include bank demand deposits and money market funds that invest in U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

Concentrations of Credit Risk and Significant Suppliers

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains its cash and cash equivalents with a financial institution that management believes is creditworthy. The Company's investment policy includes guidelines on the quality of the financial institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

Fair Value Measurement

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

[Table of Contents](#)

Level 2—Observable inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determination of fair value of the assets or liabilities.

Cash, cash equivalents and restricted cash are Level 1 assets which are comprised of funds held in checking and money market accounts. Cash, cash equivalents and restricted cash were recorded at fair value as disclosed in Note 3. The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term maturities.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the asset. The Company estimates the useful life of its assets as follows:

Asset	Estimated useful life
Laboratory equipment	Five years
Office furniture and fixtures	Five years
Computer hardware	Two years
Leasehold improvements	Shorter of useful life or remaining lease term

Maintenance and repairs that do not improve or extend the life of the respective asset are expensed to operations as incurred. Upon disposal of an asset, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations.

Other Assets

Other assets consists primarily of bank deposits of \$107, classified as restricted cash, to collateralize a letter of credit.

Impairment of Long-lived Assets

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book value of the assets to the estimated undiscounted future net cash flows that the asset is expected to generate. If the estimated undiscounted future net cash flows are less than the book value, the asset is impaired, and the impairment loss to be recognized in income is measured as the amount by which the book value of the asset exceeds its fair value, which is measured based on the estimated discounted future net cash flows that the asset is expected to generate. No impairment losses were recorded during the years ended December 31, 2019 and 2018.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist principally of costs associated with outsourced research and development activities, including preclinical and clinical development, manufacturing and research conducted by contract research organizations and academic institutions, employee compensation and consulting expenses together with related expenses, professional fees and facility and overhead costs. Facility and overhead costs primarily include the allocation of rent, utility and office-related expenses attributable to research and development personnel. In circumstances where amounts

[Table of Contents](#)

have been paid in advance or in excess of costs incurred, the Company records a prepaid expense, which is expensed as services are performed or goods are delivered.

The Company has entered into various research and development contracts with third parties. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase of completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

Costs to secure and maintain the Company's patents are expensed as incurred and are classified as general and administrative expenses in the Company's consolidated statements of operations.

Stock-based Compensation

Stock-based compensation expense is classified in the consolidated statement of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified. Stock-based awards granted to employees and non-employees are measured based on the estimated fair value of the awards using the Black-Scholes option pricing model, or Black-Scholes. Stock-based compensation expense with respect to awards with service conditions is recognized using the straight-line method over the service period. Stock-based compensation with respect to awards with performance conditions is recognized when satisfaction of the performance conditions is probable. Stock-based compensation is based on awards ultimately expected to vest and, as such, it is reduced by forfeitures. The Company accounts for forfeitures as they occur.

Black-Scholes requires the use of subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Fair value of common stock—Historically, because there has been no public market for the Company's common stock, the fair value of the Company's common stock underlying stock-based awards was estimated on each grant date by the board of directors.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of a stock-based award.

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding. Given the Company's lack of specific history, the expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards.

Expected volatility—Since the Company is privately held and does not have any trading history for its common stock, the expected volatility is estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock-based awards. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected dividend yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base. Deferred tax assets, which relate primarily to the carrying amount of the Company's net operating loss carryforwards, are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax expense or benefit is the result of changes in the deferred tax assets and liabilities. Valuation allowances are established to reduce deferred tax assets where, based upon the available evidence, the Company concludes that it is more-likely-than-not that the deferred tax assets will not be realized. In evaluating its ability to recover deferred tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income.

Reserves are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more-likely-than-not to be sustained on examination by a taxing authority. Interest and penalties related to uncertain tax positions are recognized in the provision of income taxes.

Comprehensive Loss

Comprehensive income (loss) includes net income (loss) as well as other changes in stockholder equity (deficit) that result from transactions and economic events other than those with equity holders. The Company did not have any items of comprehensive income or loss other than net loss for the years ended December 31, 2019 and 2018.

Net Loss Per Share Attributable to Common Stockholders

The Company calculates basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for participating securities. The Company considers its convertible preferred stock to be participating securities as, in the event a dividend is paid on common stock, the holders of convertible preferred stock would be entitled to receive dividends on a basis consistent with the common stockholders. Under the two-class method, the net loss attributable to common stockholders is not allocated to the convertible preferred stock as the holders of the convertible preferred stock do not have a contractual obligation to share in losses.

Since inception, the Company has incurred recurring operating losses and, as such, under the two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock. Under the two-class method, for periods with net income, basic net income per common share is computed by dividing the net income attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Net income attributable to common stockholders is computed by subtracting from net income the portion of current year earnings that the participating securities would have been entitled to receive pursuant to their dividend rights had all of the year's earnings been distributed. No such adjustment to earnings is made during periods with a net loss, as the holders of the participating securities have no obligation to fund losses. Diluted net loss per common share is computed by using the weighted-average number of shares of common stock outstanding. Due to net losses for the year ended December 31, 2019 and 2018, basic and diluted net loss per share attributable to common stockholders were the same, as the effect of all potentially dilutive securities would have been anti-dilutive.

Unaudited Pro Forma Information

Upon closing of a qualified public offering, all of the Company's outstanding shares of convertible preferred stock will automatically convert into shares of common stock. The unaudited pro forma basic and diluted net loss per share were computed using the weighted average number of common shares outstanding after giving effect to the conversion of all the convertible preferred stock into shares of common stock as if such conversion had occurred at the beginning of the period presented or the date of original issuance, if later.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker, or CODM, in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer, who manages and allocates resources to the operations on a total company basis. Accordingly, there is a single operating segment and one reportable segment.

Emerging Growth Company Status

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

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *Leases*, 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. 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 standard is effective for the Company beginning January 1, 2021, with early adoption permitted. The Company is currently evaluating the expected impact that the standard could have on its consolidated financial statements and related disclosures.

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. 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 standard is effective for the Company beginning January 1, 2021, with early adoption permitted. The Company is currently evaluating the expected impact that the standard could have on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) (“ASU 2014-09”), which supersedes existing revenue recognition guidance under GAAP. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle and will require companies to use more judgment and make more estimates than under the current guidance. The Company expects that these judgments and estimates will include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers* (Topic 606): *Deferral of the Effective Date*, which delays the effective date of ASU 2014-09 such that the standard is effective for annual periods beginning after December 15, 2018. The FASB subsequently issued amendments to ASU 2014-09 that have the same effective date and transition date. The Company adopted ASU 2014-09 as of January 1, 2019 and the adoption did not have an impact on the Company’s consolidated financial statements as the Company does not currently have any revenue-generating arrangements.

In August 2018, the FASB issued ASU 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurements*, which changes the fair value measurement disclosure requirements of ASC 820. The goal of the ASU is to improve the effectiveness of ASC 820’s disclosure requirements. The standard is applicable to the Company for fiscal years beginning January 1, 2020 and interim periods within those years. The Company elected to early adopt this guidance effective January 1, 2019. The adoption of this guidance did not have an effect the Company’s consolidated financial statements.

3. 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 December 31, 2019			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$21,038	\$ —	\$ —	\$21,038
Total cash equivalents	\$21,038	\$ —	\$ —	\$21,038

	Fair Value Measurements as of December 31, 2018			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$33,398	\$ —	\$ —	\$33,398
Total cash equivalents	\$33,398	\$ —	\$ —	\$33,398

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 consolidated balance sheets as of December 31, 2019 and 2018.

There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2019 and 2018.

4. Property and Equipment, net

Property and equipment, net, consist of the following:

	December 31,	
	2019	2018
Laboratory equipment	\$ 5	\$ 5
Office furniture and fixtures	13	13
Computer hardware	11	9
Leasehold improvements	125	125
Total property and equipment, at cost	154	152
Less: accumulated depreciation and amortization	(113)	(96)
Property and equipment, net	\$ 41	\$ 56

Depreciation and amortization expense was \$17 for each of the years ended December 31, 2019 and 2018.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31,	
	2019	2018
Research and development	\$1,326	\$1,026
License fees (Note 6)	200	200
Professional fees and other	361	143
Total accrued expenses and other current liabilities	\$1,887	\$1,369

6. Commitments and Contingencies

Operating Lease Agreements

The Company leases an office facility under a non-cancelable operating lease that expires July 2022. The office lease includes commitments obligating the Company to pay a pro rata share of certain building operating costs and annual rent escalations which will result in higher lease payments in future years. Rent expense is recognized on a straight-line basis over the term of the lease with the difference between expense and the payments recorded as deferred rent, which is included in accrued expenses and other current liabilities and other liabilities.

As of December 31, 2019, future minimum payments for operating leases are as follows:

2020	\$335
2021	340
2022	200
Total future minimum lease payments	\$875

Rent expense recognized under all operating leases was \$305 and \$316 for the years ended December 31, 2019 and 2018, respectively.

[Table of Contents](#)

The Company is required to maintain a letter of credit for the duration of the office lease. The Company maintains bank deposits of \$107 to collateralize the letter of credit which are classified as restricted cash and a long-term asset in the consolidated balance sheet as of December 31, 2019.

License Agreement with NovaMedica LLC

In May 2014, the Company entered into an exclusive license agreement with NovaMedica LLC, an affiliated entity of a stockholder, pursuant to which the Company granted NovaMedica a license to certain intellectual property rights for commercialization of a potential product for the treatment of hepatitis C. In connection with the license, the Company received a license fee of \$200 in partial consideration for the grant of the license. Recognition of the license fee has been deferred and recorded in other liabilities until both the Company and NovaMedica finalize certain other terms and conditions of the license agreement at which time the technology access fee will be evaluated, along with the license agreement broadly, for revenue recognition.

If the Company and NovaMedica failed to agree on the terms of an amendment to the license agreement covering certain payment terms, and the license agreement was thereafter terminated, such termination was to be subject to a payment by the Company of a termination fee of \$400. As discussed in Note 13, this agreement was terminated in May 2020, and the Company paid a termination fee of \$400.

Business Development Consulting Agreement

The Company is a party to a consulting agreement that provides for the payment by the Company of consideration, consisting of cash, up to a maximum of \$1,750, and the vesting of equity awards, if a business development transaction that meets or exceeds certain thresholds is successfully concluded on or before December 31, 2020 (Note 9). As of December 31, 2019, the performance conditions were not yet probable of being met and, as a result, no expense has yet to be recognized in connection with the consulting agreement in the consolidated statement of operations.

Indemnification

The Company enters into certain types of contracts that contingently requires 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.

7. Convertible Preferred Stock

As of December 31, 2019, the Company had 33,645,447 shares of convertible preferred stock, or Convertible Preferred Stock, authorized, of which 20,000,000 shares are designated as Series A convertible preferred

[Table of Contents](#)

stock, or Series A Preferred; 7,592,830 shares are designated as Series B convertible preferred stock, or Series B Preferred; and 6,052,617 shares are designated as Series C convertible preferred stock, or Series C Preferred. The Company's Series A Preferred, Series B Preferred and Series C Preferred were issued at \$1.00, \$3.03 and \$4.56 per share, respectively. The following table summarizes the Company's outstanding Convertible Preferred Stock:

	December 31, 2019 and 2018				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred	20,000,000	20,000,000	\$ 19,136	\$ 20,000	20,000,000
Series B Preferred	7,592,830	7,592,830	22,619	23,006	7,592,830
Series C Preferred	6,052,617	6,052,617	27,359	27,600	6,052,617
	33,645,447	33,645,447	\$ 69,114	\$ 70,606	33,645,447

The Company classifies Convertible Preferred Stock outside of stockholders' deficit because the shares contain deemed liquidation rights in the event of a merger, consolidation, or reorganization involving the Company or a subsidiary or upon the sale, lease, transfer, exclusive license or other disposition by the Company or a subsidiary of all or substantially all assets of the Company that could trigger a distribution of cash or assets and therefore a contingent redemption feature not solely within the Company's control.

The rights and preferences of Convertible Preferred Stock are described below:

Voting

Holders of the Convertible Preferred Stock preferred stock are entitled to vote, together with the holders of common stock, on all matters as to which holders of common stock are entitled to vote, except with respect to matters which Delaware General Corporation Law, or DGCL, or the certificate of incorporation requires that a vote by separate class. Each holder of Convertible Preferred Stock is entitled to one vote for each share of common stock into which the Convertible Preferred Stock is convertible at the time of such vote.

Certain actions specified in the certificate of incorporation require the affirmative vote of Requisite Preferred Holders, which are the holders of a majority of the Series B Preferred and Series C Preferred voting together as a single class, while other actions require: (i) the affirmative vote of holders of least 57% of Series C Preferred voting as a separate class; (ii) the affirmative vote of holders of at least 67% of the Series B Preferred voting as a separate class; or (iii) the affirmative vote of holders of a majority of the outstanding Convertible Preferred Stock voting as a single class.

At any time when an aggregate of 6,000,000 shares of Series B Preferred and Series C Preferred are outstanding, the affirmative vote of the Requisite Preferred Holders is required to (i) purchase, redeem or pay or declare any dividend or make any distribution on any class of stock other than certain specified transactions; or (ii) create or authorize the creation of any class or series of capital stock unless the new class ranks junior to the Series C Preferred and Series B Preferred.

At any time when at least 3,800,000 shares of Series B Preferred are outstanding, the affirmative vote of the holders of at least 67% of the Series B Preferred is required to: (i) amend, alter or repeal the certificate of incorporation or bylaws in any way that adversely affects the powers, preferences or rights of the holders of Series B Preferred; (ii) increase or decrease the authorized number of shares of Series B Preferred; and (iii) approve any liquidation event in which a holder of Series B Preferred would receive less than \$3.03 per share in connection with such event.

[Table of Contents](#)

At any time when at least 2,200,000 shares of Series C Preferred are outstanding, the affirmative vote of the holders of at least 57% of the Series C Preferred is required to: (i) amend, alter or repeal the certificate of incorporation or bylaws in any way that adversely affects the powers, preferences or rights of the holders of Series C preferred; (ii) purchase, redeem or pay or declare any dividend or make any distribution on any class of stock other than certain specified transactions; (iii) increase or decrease the authorized number of shares of Series C Preferred; and (iv) approve any liquidation event in which a holder of Series C Preferred would receive less than \$4.56 per share in connection with such event.

As long as at least 11,000,000 shares of Convertible Preferred Stock are outstanding, the affirmative vote of the holders of a majority of the outstanding Convertible Preferred Stock, voting as a single class, is required to affect any liquidation, dissolution, or winding up of the business and affairs of the Company.

The holders of Series A Preferred, Series B Preferred and the Series C Preferred, voting respectively as separate classes, each have the right to elect a director to the board of directors. The right to elect such a director shall continue for holders of Series A Preferred for so long as 5,000,000 shares of Series A Preferred are outstanding, for holders of Series B Preferred for so long as 5,000,000 shares of Series B Preferred are outstanding and for holders of Series C Preferred for so long as 2,741,228 shares of Series C Preferred are outstanding. The remainder of the board of directors, excluding one director that may be elected by holders of common stock voting as a separate class, is elected by the holders of the Convertible Preferred Stock voting together with holders of the common stock as a single class and otherwise in accordance with the stockholders' agreement.

Dividends

Holders of shares of Convertible Preferred Stock are entitled to dividends only if, when and as declared by the board of directors. The Company is prohibited from declaring, paying or setting aside any dividends unless the holders of the then outstanding Convertible Preferred Stock receive first, or simultaneously, in the case of a dividend on common stock, on a *pari passu* basis, a dividend in an amount that is at least equal to the amount that would have been received by the holders of the Convertible Preferred Stock had all the Convertible Preferred Stock been converted to common stock. As of December 31, 2019, no dividends have been declared or paid on the Convertible Preferred Stock.

Liquidation Preference

In the event of any liquidation, dissolution, winding up of the affairs or deemed liquidation event of the Company, the holders of Series C Preferred are entitled to receive in preference to the holders of Series A Preferred and Series B Preferred and the common stock, an amount equal to the greater of (1) the original purchase price of the Series C Preferred plus all declared but unpaid dividends, or (2) such amount per share of Series C Preferred payable as if converted into common stock. After the preferential payment to holders of the Series C Preferred, the holders of Series A Preferred and Series B Preferred, on a *pari passu* basis and prior and in preference to the holders of common stock, are entitled to receive an amount equal to the greater of (1) the original purchase price of the applicable series of preferred stock plus all declared but unpaid dividends, or (2) such amount per share of preferred stock payable as if converted into common stock. After the preferential distributions are made to the holders of Convertible Preferred Stock, any remaining assets of the Company will be distributed ratably among the holders of common stock. If the assets or surplus funds to be distributed to the holders of the Convertible Preferred are insufficient to permit the payment to such holders of their full preferential amount, the assets and surplus funds legally available for distribution will be distributed in preferential order, first to the holders of Series C Preferred and next to the holders of Series A Preferred and Series B Preferred, in each instance, ratably in proportion to the respective amount that would have been paid if all amounts payable on or with respect to such shares had been paid in full.

[Table of Contents](#)

In the event of a deemed liquidation event, holders of Convertible Preferred Stock may require the Company to redeem their shares at a price equal to the liquidation amount.

Conversion

Each share of Convertible Preferred Stock is convertible into common stock on a one-for-one basis. Conversion is at the option of the holder of the Convertible Preferred Stock except upon either the closing of a firm commitment underwritten public offering in which shares of common stock are sold at a price of at least \$5.48 per share (subject to appropriate adjustment for stock splits, stock dividends, combinations and other similar recapitalizations affecting the number of such shares issued and outstanding) resulting in gross proceeds of at least \$50 million, or upon the written election of the Requisite Preferred Holders in which event conversion of Series A Preferred and Series B Preferred is automatic and Series C Preferred will convert provided that holders of at least 57% of then outstanding Series C Preferred consent to such conversion. The conversion price of each of the Series C Preferred, Series B Preferred and Series A Preferred at December 31, 2019 is equal to the respective original issue price of each series.

The conversion price is subject to adjustment in accordance with provisions in the certificate of incorporation. Specifically, the holders of Convertible Preferred Stock are entitled to weighted average anti-dilution protection in the event that the Company issues additional securities at a purchase price less than the then effective conversion price.

Registration Rights

The holders of the Convertible Preferred Stock may require the Company in certain circumstances to register for sale the shares of common stock issuable upon conversion of the Convertible Preferred Stock. Such registration would permit the sale of the underlying common stock under the Securities Act of 1933, as amended.

Participation Rights in Future Equity Issuances

All holders of Convertible Preferred Stock have a pro rata right, based on their percentage equity ownership in the Company, to participate, subject only to certain limited exceptions, in subsequent issuances of equity securities of the Company. In addition, should any such holder choose not to purchase its full pro rata share, the remaining holders of Convertible Preferred Stock have the right to purchase the remaining pro rata shares.

Redemption rights

Convertible Preferred Stock has no stated redemption features. However, the Convertible Preferred Stock does contain deemed liquidation rights in the event of a merger, consolidation, or reorganization involving the Company or a subsidiary or on the sale, lease, transfer, exclusive license or other disposition by the Company or a subsidiary of all or substantially all assets of the Company that could trigger a distribution of cash or assets not solely within the Company's control.

8. Common Stock

At December 31, 2019, the authorized capital of the Company included 53,070,161 shares of common stock, of which 10,091,100 shares of common stock were considered issued and outstanding for accounting purposes. As discussed in Note 9, restricted stock awards for an aggregate 200,000 shares are excluded from issued and outstanding shares for accounting purposes. On all matters to be voted upon by the holders of common stock, holders of common stock are entitled to one vote per share. Subject to the rights and preferences applicable to the outstanding shares of Convertible Preferred Stock, the holders of common stock are entitled to receive dividends, when declared by the board, and to share ratably in the Company's assets legally available for

[Table of Contents](#)

distribution to the holders of the Company's stock in the event of liquidation. The holders of common stock have no preemptive, redemption or conversion rights.

The Company had the following reserved shares of common stock:

	December 31, 2019
Series A Preferred	20,000,000
Series B Preferred	7,592,830
Series C Preferred	6,052,617
Outstanding options	3,911,633
Options available for future grant	450,567
	<u>38,007,647</u>

9. Stock-based Compensation

As of December 31, 2019, the Atea Pharmaceuticals 2013 Equity Incentive Plan, as amended, or 2013 Plan, provides 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.

As of December 31, 2019, options to purchase 3,986,633 shares of common stock and 3,370,000 shares of restricted common stock have been granted under the 2013 Plan, and there were 450,567 shares of common stock remaining available for future issuance.

Restricted Common Stock

Restricted stock awards generally include vesting and risk of forfeiture provisions that lapse upon satisfaction of performance conditions or over time periods commencing on the grant date and concluding on the third or fourth anniversary of the grant date.

The Company has granted awards totaling 200,000 shares of restricted common stock to a consultant pursuant to the 2013 Plan for consulting and business development services. The consultant paid \$1.21 per share and an aggregate of \$121 for 100,000 of the shares of restricted common stock in 2016 and \$1.24 per share and an aggregate of \$124 for 100,000 of the shares of restricted common stock in 2018. These awards of restricted common stock will vest, and the risk of forfeiture will lapse upon satisfaction of performance conditions detailed in each award. As of December 31, 2019, the performance conditions were not yet probable of being met and, as a result, no compensation expense has yet been recognized for these performance-based awards. The unvested and forfeitable common stock as of December 31, 2019 and 2018, though legally issued, are excluded from issued and outstanding shares for accounting purposes. Amounts received for the unvested and forfeitable common stock totaling \$245 are included in additional paid-in capital within stockholders' deficit in the consolidated balance sheets. At December 31, 2019, total unrecognized compensation expense related to unvested restricted common stock was \$370.

Stock Options

The following summarizes stock option activity:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2019	2,820,000	\$ 1.40	8.9	\$ 2,059
Granted	1,091,633	\$ 1.78		
Outstanding at December 31, 2019	3,911,633	\$ 1.50	8.5	\$ 3,915
Options exercisable at December 31, 2019	1,967,824	\$ 1.37	7.7	\$ 2,252
Vested or expected to vest at December 31, 2019	3,911,633	\$ 1.50	8.5	\$ 3,915

The aggregate intrinsic value of options granted is calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock.

Option grants generally vest over a service period of three or four years and have a contractual term of ten years. There were no options exercised, forfeited or expired during the years ended December 31, 2019 and 2018. As of December 31, 2019, total unrecognized compensation expense related to stock option awards was \$1,927, which amount is being recognized over a remaining weighted average period of 2.5 years.

The weighted average grant date fair value per option granted to employees during the years ended December 31, 2019 and 2018 was \$1.19 and \$0.774, respectively. The fair value of each award was estimated using Black-Scholes based on the following assumptions:

	For the Year Ended December 31,	
	2019	2018
Risk-free interest rate	1.61 - 2.02%	2.45 - 2.89%
Expected term	5.52 - 10.0 years	5.52 - 9.96 years
Expected volatility	49.2% - 78.0%	49.2%
Expected dividend yield	0%	0%

Stock-based Compensation Expense

Stock-based compensation expense is classified as follows:

	For the Year Ended December 31,	
	2019	2018
Research and development expense	\$ 255	\$ 192
General and administrative	369	222
Total stock-based compensation expense	\$ 624	\$ 414

[Table of Contents](#)

The components of stock-based compensation expense were:

	For the Year Ended December 31,	
	2019	2018
Restricted common stock	\$ —	\$ 5
Stock options	624	409
Total stock-based compensation expense	\$ 624	\$ 414

10. Income Taxes

During the years ended December 31, 2019 and 2018, the Company did not record a current or deferred income tax expense or benefit.

The reconciliation of federal statutory income tax rate to the Company's effective income tax rate is as follows:

	For the Year Ended December 31,	
	2019	2018
Federal statutory income tax rate	21.0%	21.0%
State taxes	6.2	4.0
Research and development credits	0.9	1.1
Other	(0.5)	0.3
Change in valuation allowance	(27.6)	(26.4)
Total	0.0%	0.0%

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's deferred tax assets consisted of the following:

	December 31,	
	2019	2018
Deferred tax assets		
Net operating loss carryforwards	\$ 13,466	\$ 9,617
Stock-based compensation	1,024	918
Research and development credits	455	335
Other	152	352
Gross deferred tax assets	15,097	11,222
Less: valuation allowance	(15,097)	(11,222)
Net deferred tax assets	\$ —	\$ —

As of December 31, 2019, the Company had federal net operating losses of \$49,309 and state net operating loss carryforwards of \$49,219. The Company also has federal and state research and development tax credit carryforwards of \$348 and \$136, respectively, which may be used to offset future tax liabilities. Federal net operating losses generated prior to 2018 of \$27,522 can be carried back two years and carried forward 20 years. Federal net operating losses and federal tax credit carryforwards generated prior to 2018 will begin to expire in 2033. Federal net operating losses generated post 2017 of \$21,787 can be carried forward indefinitely but can only offset 80 percent of annual taxable income. State net operating losses will begin to expire in 2033 and state tax credit carryforwards will begin to expire in 2031.

[Table of Contents](#)

Management has evaluated the positive and negative evidence bearing upon the realizability of the Company's deferred tax assets, which are comprised principally of net operating loss carryforwards. Based on the Company's cumulative net losses since inception and its lack of revenue generating commercial products, the Company determined that it is more likely than not that it will not recognize the benefits of the deferred tax assets. As a result, the Company has recorded a full valuation allowance of approximately \$15,097 at December 31, 2019. The Company increased its valuation allowance by \$3,875 for the year ended December 31, 2019 in order to maintain a full valuation allowance against its deferred tax assets.

Under the provisions of Sections 382 and 383 of the Internal Revenue Code, or IRC, net operating loss and credit carryforwards and other tax attributes may be subject to limitation if there has been a significant change in ownership of the Company, as defined by the IRC. Future owner or equity shifts, including an initial public offering, could result in limitations on net operating loss and credit carryforwards.

The Company performed an analysis through December 31, 2018 pursuant to Section 382 of the IRC to determine whether any limitations might exist on the utilization of net operating losses and other tax attributes. Based on this analysis, the Company has determined that ownership changes occurred in 2014, resulting in an annual limitation of \$169 on the use of its net operating losses and other tax attributes generated prior to the ownership change. To the extent that the Company raises additional equity financing or other changes in the ownership interest of significant stockholders occurs, additional tax attributes may become subject to an annual limitation. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

The Company files federal and Commonwealth of Massachusetts state income tax returns. The statute of limitations for assessment by the Internal Revenue Service, or IRS, and state tax authorities remains open for all tax years ended since the inception of the Company. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the IRS or state tax authorities to the extent utilized in a future period. No federal or state tax audits are currently in process.

The Company evaluates tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information. The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2019 nor has it recorded any penalties or interest.

11. Net Loss Per Share Attributable to Common Stockholders and Unaudited Pro Forma Information

Net Loss Per Share Attributable to Common Stockholders

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	For the Year Ended December 31,	
	2019	2018
Convertible Preferred Stock	33,645,447	33,645,447
Stock options to purchase common stock	3,911,633	2,820,000
Non-vested restricted stock	200,000	200,000

Unaudited Pro Forma Information

The calculation of weighted average shares outstanding for purposes of calculating pro forma net loss per share attributable to common stockholders for the year ended December 31, 2019 assumes the conversion of 33,645,447 into common shares effective January 1, 2019.

12. Related Party Transactions

For the year ended December 31, 2019, the Company recorded expense of \$145 for consulting services provided by an entity affiliated with its interim Chief Financial Officer, of which \$20 is included in accrued expenses and other current liabilities as of December 31, 2019.

Except as disclosed in Note 6 in the notes to the accompanying consolidated financial statements, there were no other material transactions with related parties.

13. Subsequent Events

In February 2020, the Company entered into 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.

In May 2020, the Company filed an amendment to its certificate of incorporation to increase the authorized common stock to 80,529,575 shares and authorize 15,313,382 shares of Series D Preferred and 8,973,261 shares of Series D-1 convertible preferred stock ("Series D-1 Preferred"). The Company entered into a stock purchase agreement with certain investors and issued 15,313,382 shares of Series D Preferred for gross proceeds of \$107,500. Upon the achievement of a clinical trial milestone, as defined in the stock purchase agreement, the investors will be obligated to purchase 2,991,087 shares of Series D-1 Preferred for gross proceeds of \$35,833. In addition, the investors will have the right to purchase up to 5,982,174 shares of Series D-1 Preferred ("Additional Series D-1 Preferred") at a price of \$11.98 per share following achievement of the clinical development milestone discussed above and the receipt of certain preclinical data as defined in the stock purchase agreement. Unless previously exercised, the option to purchase the Additional Series D-1 Preferred will terminate eight days after the filing of a registration statement for an initial public offering of the Company's common stock.

In May 2020, the Company and Novamedica terminated the license agreement discussed in Note 6. The Company paid a termination fee of \$400 in connection with the termination.

ATEA PHARMACEUTICALS, INC.**Consolidated Balance Sheets**

(in thousands, except share and per share amounts)

(Unaudited)

	June 30, 2020	December 31, 2019	Pro Forma June 30, 2020
Assets			
Current assets			
Cash and cash equivalents	\$ 115,792	\$ 21,661	\$ 115,792
Prepaid expenses and other current assets	2,658	249	2,658
Total current assets	118,450	21,910	118,450
Property and equipment, net	39	41	39
Other assets	1,256	122	1,256
Total assets	\$ 119,745	\$ 22,073	\$ 119,745
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)			
Current liabilities			
Accounts payable	\$ 3,860	\$ 548	\$ 3,860
Accrued expenses and other current liabilities	3,198	1,887	3,198
Total current liabilities	7,058	2,435	7,058
Other liabilities	69	95	69
Total liabilities	7,127	2,530	7,127
Commitments and contingencies (see Note 6)			
Convertible preferred stock, \$0.001 par value; 57,932,090 and 33,645,447 shares authorized as of June 30, 2020 and December 31, 2020, respectively; 48,958,829 and 33,645,447 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively; liquidation preference of \$178,106 and \$70,606 as of June 30, 2020 and December 31, 2019, respectively; no shares authorized, issued or outstanding pro forma as of June 30, 2020	175,745	69,114	—
Stockholders' equity (deficit):			
Common stock, \$0.001 par value; 80,529,575 and 53,070,161 shares authorized as of June 30, 2020 and December 31, 2019, respectively; 10,109,847 and 10,091,100 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively; 59,068,676 shares issued and outstanding pro forma as of June 30, 2020	10	10	59
Additional paid-in capital	5,057	4,632	180,753
Accumulated deficit	(68,194)	(54,213)	(68,194)
Total stockholders' equity (deficit)	(63,127)	(49,571)	112,618
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 119,745	\$ 22,073	\$ 119,745

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

ATEA PHARMACEUTICALS, INC.**Consolidated Statements of Operations and Comprehensive Loss**

(in thousands, except share and per share amounts)

(Unaudited)

	Six Months Ended June 30,	
	2020	2019
Operating expenses		
Research and development	\$ 10,576	\$ 4,270
General and administrative	3,472	1,820
Total operating expenses	14,048	6,090
Loss from operations	(14,048)	(6,090)
Interest income and other, net	67	343
Net loss and comprehensive loss	\$ (13,981)	\$ (5,747)
Net loss per share attributable to common stockholders—basic and diluted	\$ (1.39)	\$ (0.57)
Weighted-average common shares outstanding—basic and diluted	10,093,689	10,091,100
Pro forma net loss per share attributable to common stockholders—basic and diluted	\$ (0.30)	
Pro forma weighted-average common shares outstanding—basic and diluted	47,292,517	

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

ATEA PHARMACEUTICALS, INC.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit

(in thousands, except share amounts)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance—December 31, 2018	33,645,447	\$ 69,114	10,091,100	\$ 10	\$ 4,008	\$ (40,179)	\$ (36,161)
Stock-based compensation expense	—	—	—	—	293	—	293
Net loss	—	—	—	—	—	(5,747)	(5,747)
Balance—June 30, 2019	33,645,447	\$ 69,114	10,091,100	\$ 10	\$ 4,301	\$ (45,926)	\$ (41,615)
Balance—December 31, 2019	33,645,447	\$ 69,114	10,091,100	\$ 10	\$ 4,632	\$ (54,213)	\$ (49,571)
Issuance of Series D convertible preferred stock, net of issuance costs of \$869	15,313,382	106,631	—	—	—	—	—
Issuance of common stock for exercise of stock options	—	—	18,747	—	27	—	27
Stock-based compensation expense	—	—	—	—	398	—	398
Net loss	—	—	—	—	—	(13,981)	(13,981)
Balance—June 30, 2020	48,958,829	\$ 175,745	10,109,847	\$ 10	\$ 5,057	\$ (68,194)	\$ (63,127)

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

ATEA PHARMACEUTICALS, INC.

Consolidated Statements of Cash Flows

(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (13,981)	\$ (5,747)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	398	293
Depreciation and amortization expense	8	9
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(2,409)	17
Accounts payable	2,643	327
Accrued expenses and other liabilities	1,035	(106)
Net cash used in operating activities	<u>(12,306)</u>	<u>(5,207)</u>
Cash flows from investing activities		
Additions to property and equipment	(6)	—
Net cash used in investing activities	<u>(6)</u>	<u>—</u>
Cash flows from financing activities		
Proceeds from issuance of convertible preferred stock, net of issuance costs	106,631	—
Proceeds from issuance of common stock for exercise of stock options	27	—
Payments of deferred offering costs	(215)	—
Net cash used in financing activities	<u>106,443</u>	<u>—</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	94,131	(5,207)
Cash, cash equivalents and restricted cash at the beginning of period	21,768	34,599
Cash, cash equivalents and restricted cash at the end of period	<u>\$ 115,899</u>	<u>\$ 29,392</u>
Cash, cash equivalents and restricted cash at the end of period		
Cash and cash equivalents	\$ 115,792	\$ 29,285
Restricted cash	107	107
Total cash, cash equivalents and restricted cash	<u>\$ 115,899</u>	<u>\$ 29,392</u>
Supplemental disclosure of noncash financing activities		
Equity issuance costs included in accounts payable and accrued expenses	\$ 919	\$ —

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

ATEA PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements

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

(Unaudited)

1. Nature of Organization

Organization

Atea Pharmaceuticals, Inc. (together with its subsidiary, "Atea" or "the Company"), is a biopharmaceutical company that was incorporated in July 2012 and began principal operations in March 2014. The Company is using a chemistry driven approach and its drug discovery and development capabilities to identify and develop novel antiviral therapeutics. The Company is located in Boston, Massachusetts. Atea Pharmaceuticals Securities Corporation, or Atea PSC, a Massachusetts corporation incorporated in 2016, is a wholly owned subsidiary of Atea.

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. 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 our 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 has financed its operations to date primarily from the sale of convertible preferred stock. Since its inception, the Company has incurred recurring operating losses and negative cash flows from operations. As of June 30, 2020, the Company had an accumulated deficit of \$68,194. The Company expects to continue to generate operating losses for the foreseeable future. Management believes its existing cash resources will be sufficient to fund its operations as currently planned for at least twelve months following the issuance of these financial statements.

The Company is seeking to complete an initial public offering, or IPO, of its common stock. In the event that the Company does not complete an IPO, the Company may seek additional capital through one or more of a combination of private financing through the sale of additional equity securities, debt financing or funding in connection with any 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.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying unaudited consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP.

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 accrued research and development expenses and the valuation of common stock in connection with the issuance of stock-based awards. 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 the Company and Atea PSC. All intercompany amounts have been eliminated in consolidation.

Unaudited Interim Financial Information

The accompanying balance sheet as of June 30, 2020 and the statements of operations and comprehensive loss and of cash flows for the six months ended June 30, 2020 and 2019 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 June 30, 2020 and the results of its operations and its cash flows for the six months ended June 30, 2020 and 2019. The results for the six months ended June 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, any other interim periods, or any future year or period.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include bank demand deposits and money market funds that invest in U.S. government and U.S. government agency obligations. Cash equivalents are reported at fair value.

Concentrations of Credit Risk and Significant Suppliers

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents. The Company maintains its cash and cash equivalents with a financial institution that management believes is creditworthy. The Company's investment policy includes guidelines on the quality of the financial institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

[Table of Contents](#)

Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Observable inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determination of fair value of the assets or liabilities.

Cash, cash equivalents and restricted cash are Level 1 assets which are comprised of funds held in checking and money market accounts. Cash, cash equivalents and restricted cash were recorded at fair value as disclosed in Note 3. The carrying amounts of accounts payable and accrued expenses approximate their fair values due to their short-term maturities.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the asset. The Company estimates the useful life of its assets as follows:

Asset	Estimated useful life
Laboratory equipment	Five years
Office furniture and fixtures	Five years
Computer hardware	Two years
Leasehold improvements	Shorter of useful life or remaining lease term

Maintenance and repairs that do not improve or extend the life of the respective asset are expensed to operations as incurred. Upon disposal of an asset, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations.

Other Assets

The Company capitalizes incremental legal, professional, accounting and other third-party fees that are directly associated with the planned IPO as other non-current assets until the IPO is consummated. After consummation of the IPO, these costs will be recorded in stockholders' equity as a reduction of additional paid-in-capital generated as a result of the offering. If the Company terminates its plan for an IPO, any costs deferred will be expensed immediately. As of June 30, 2020, equity issuance costs of \$1,149 were included in Other assets in the accompanying consolidated balance sheet. Also included in Other assets is restricted cash of \$107, to collateralize a letter of credit.

Impairment of Long-lived Assets

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book value of the assets to the estimated undiscounted future net cash flows that the asset is expected to generate. If the estimated undiscounted future net cash flows are less than the book value, the asset is impaired, and the impairment loss to be recognized in income is measured as the amount by which the book value of the asset exceeds its fair value, which is measured based on the estimated discounted future net cash flows that the asset is expected to generate. No impairment losses were recorded during the six months ended June 30, 2020 and 2019.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist principally of costs associated with outsourced research and development activities, including preclinical and clinical development, manufacturing and research conducted by contract research organizations and academic institutions, employee compensation and consulting expenses together with related expenses, professional fees and facility and overhead costs. Facility and overhead costs primarily include the allocation of rent, utility and office-related expenses attributable to research and development personnel. In circumstances where amounts have been paid in advance or in excess of costs incurred, the Company records a prepaid expense, which is expensed as services are performed or goods are delivered.

The Company has entered into various research and development contracts with third parties. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase of completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

Costs to secure and maintain the Company's patents are expensed as incurred and are classified as general and administrative expenses in the Company's consolidated statements of operations.

Stock-based Compensation

Stock-based compensation expense is classified in the consolidated statement of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified. Stock-based awards granted to employees and non-employees are measured based on the estimated fair value of the awards using the Black-Scholes option pricing model, or Black-Scholes. Stock-based compensation expense with respect to awards with service conditions is recognized using the straight-line method over the service period. Stock-based compensation with respect to awards with performance conditions is recognized when satisfaction of the performance conditions is probable. Stock-based compensation is based on awards ultimately expected to vest and, as such, it is reduced by forfeitures. The Company accounts for forfeitures as they occur.

Black-Scholes requires the use of subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Fair value of common stock—Historically, because there has been no public market for the Company's common stock, the fair value of the Company's common stock underlying stock-based awards was estimated on each grant date by the board of directors.

[Table of Contents](#)

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of a stock-based award.

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding. Given the Company's lack of specific history, the expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards.

Expected volatility—Since the Company is privately held and does not have any trading history for its common stock, the expected volatility is estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock-based awards. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected dividend yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base. Deferred tax assets, which relate primarily to the carrying amount of the Company's net operating loss carryforwards, are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax expense or benefit is the result of changes in the deferred tax assets and liabilities. Valuation allowances are established to reduce deferred tax assets where, based upon the available evidence, the Company concludes that it is more-likely-than-not that the deferred tax assets will not be realized. In evaluating its ability to recover deferred tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income.

Reserves are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more-likely-than-not to be sustained on examination by a taxing authority. Interest and penalties related to uncertain tax positions are recognized in the provision of income taxes.

Comprehensive Loss

Comprehensive income (loss) includes net income (loss) as well as other changes in stockholder equity (deficit) that result from transactions and economic events other than those with equity holders. The Company did not have any items of comprehensive income or loss other than net loss for the six months ended June 30, 2020 and 2019.

Net Loss Per Share Attributable to Common Stockholders

The Company calculates basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for participating securities. The Company considers its convertible preferred stock to be participating securities as, in the event a dividend is paid on common stock, the holders of convertible preferred stock would be entitled to receive dividends on a basis consistent with the common stockholders. Under the two-class method, the net loss attributable to common stockholders is not allocated to the convertible preferred stock as the holders of the convertible preferred stock do not have a contractual obligation to share in losses.

[Table of Contents](#)

Since inception, the Company has incurred recurring operating losses and, as such, under the two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock. Under the two-class method, for periods with net income, basic net income per common share is computed by dividing the net income attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Net income attributable to common stockholders is computed by subtracting from net income the portion of current year earnings that the participating securities would have been entitled to receive pursuant to their dividend rights had all of the year's earnings been distributed. No such adjustment to earnings is made during periods with a net loss, as the holders of the participating securities have no obligation to fund losses. Diluted net loss per common share is computed by using the weighted-average number of shares of common stock outstanding. Due to net losses for the six months ended June 30, 2020 and 2019, basic and diluted net loss per share attributable to common stockholders were the same, as the effect of all potentially dilutive securities would have been anti-dilutive.

Pro Forma Information

Upon closing of a qualified public offering, all of the Company's outstanding shares of convertible preferred stock will automatically convert into shares of common stock. The accompanying unaudited pro forma condensed consolidated balance sheet as of June 30, 2020 has been prepared to give effect to the conversion of all outstanding shares of the Company's preferred stock into an aggregate of 48,958,829 shares of common stock as if the conversion had occurred on June 30, 2020. The unaudited pro forma basic and diluted net loss per share were computed using the weighted average number of common shares outstanding after giving effect to the conversion of all the convertible preferred stock into shares of common stock as if such conversion had occurred at the beginning of the period presented or the date of original issuance, if later.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker, or CODM, in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer, who manages and allocates resources to the operations on a total company basis. Accordingly, there is a single operating segment and one reportable segment.

Emerging Growth Company Status

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

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *Leases*, 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

[Table of Contents](#)

period presented in the financial statements, with certain practical expedients available. 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 standard is effective for the Company beginning January 1, 2021, with early adoption permitted. The Company is currently evaluating the expected impact that the standard could have on its consolidated financial statements and related disclosures.

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. 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 standard is effective for the Company beginning January 1, 2021, with early adoption permitted. The Company is currently evaluating the expected impact that the standard could have on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) (“ASU 2014-09”), which supersedes existing revenue recognition guidance under GAAP. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle and will require companies to use more judgment and make more estimates than under the current guidance. The Company expects that these judgments and estimates will include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delays the effective date of ASU 2014-09 such that the standard is effective for annual periods beginning after December 15, 2018. The FASB subsequently issued amendments to ASU 2014-09 that have the same effective date and transition date. The Company adopted ASU 2014-09 as of January 1, 2019 and the adoption did not have an impact on the Company’s consolidated financial statements as the Company does not currently have any revenue-generating arrangements.

In August 2018, the FASB issued ASU 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurements*, which changes the fair value measurement disclosure requirements of ASC 820. The goal of the ASU is to improve the effectiveness of ASC 820’s disclosure requirements. The standard is applicable to the Company for fiscal years beginning January 1, 2020, and interim periods within those years. The Company elected to early adopt this guidance effective January 1, 2019. The adoption of this guidance did not have an effect the Company’s consolidated financial statements.

3. 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 June 30, 2020			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$106,603	\$ —	\$ —	\$106,603
Total cash equivalents	\$106,603	\$ —	\$ —	\$106,603

	Fair Value Measurements as of December 31, 2019			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$21,038	\$ —	\$ —	\$21,038
Total cash equivalents	\$21,038	\$ —	\$ —	\$21,038

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 consolidated balance sheets as of June 30, 2020 and December 31, 2019.

There were no transfers among Level 1, Level 2 or Level 3 categories in the six months ended June 30, 2020 and 2019.

4. Property and Equipment, net

Property and equipment, net, consist of the following:

	June 30, 2020	December 31, 2019
Laboratory equipment	\$ 5	\$ 5
Office furniture and fixtures	13	13
Computer hardware	17	11
Leasehold improvements	125	125
Total property and equipment, at cost	160	154
Less: accumulated depreciation and amortization	(121)	(113)
Property and equipment, net	\$ 39	\$ 41

Depreciation and amortization expense was \$8 and \$9 for the six months ended June 30, 2020 and 2019, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	June 30, 2020	December 31, 2019
Research and development	\$ 2,169	\$ 1,326
License fees (Note 6)	—	200
Professional fees and other	631	361
Payroll and payroll related	398	—
Total accrued expenses and other current liabilities	\$ 3,198	\$ 1,887

6. Commitments and Contingencies

Operating Lease Agreements

The Company leases an office facility under a non-cancelable operating lease that expires July 2022. The office lease includes commitments obligating the Company to pay a pro rata share of certain building operating costs and annual rent escalations which will result in higher lease payments in future years. Rent expense is recognized on a straight-line basis over the term of the lease with the difference between expense and the payments recorded as deferred rent, which is included in accrued expenses and other current liabilities and other liabilities.

As of June 30, 2020, future minimum payments for operating leases are as follows:

2020	\$ 169
2021	340
2022	200
Total future minimum lease payments	\$ 709

Rent expense recognized under all operating leases was \$141 and \$141 for six months ended June 30, 2020 and 2019, respectively.

The Company is required to maintain a letter of credit for the duration of the office lease. The Company maintains bank deposits of \$107 to collateralize the letter of credit which are classified as restricted cash and a long-term asset in the consolidated balance sheet as of June 30, 2020.

License Agreement with NovaMedica LLC

In May 2014, the Company entered into an exclusive license agreement with NovaMedica LLC, an affiliated entity of a stockholder, pursuant to which the Company granted NovaMedica a license to certain intellectual property rights for commercialization of a potential product for the treatment of hepatitis C. In connection with the license, the Company received a license fee of \$200 in partial consideration for the grant of the license. Recognition of the license fee has been deferred and recorded in other liabilities until both the Company and NovaMedica finalize certain other terms and conditions of the license agreement at which time the technology access fee will be evaluated, along with the license agreement broadly, for revenue recognition.

If the Company and NovaMedica failed to agree on the terms of an amendment to the license agreement covering certain payment terms, and the license agreement was thereafter terminated, such termination was to be subject to a payment by the Company of a termination fee of \$400. This agreement was terminated in May 2020, and the Company paid a termination fee of \$400.

Business Development Consulting Agreements

The Company is a party to a consulting agreement that provides for the payment by the Company of consideration, consisting of cash, up to a maximum of \$1,750, and the vesting of equity awards, if a business development transaction that meets or exceeds certain thresholds is successfully concluded on or before December 31, 2020 (Note 9). As of June 30, 2020, the performance conditions were not yet probable of being met and, as a result, no expense has yet to be recognized in connection with the consulting agreement in the consolidated statement of operations.

In February 2020, the Company entered into 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 \$5,000.

Indemnification

The Company enters into certain types of contracts that contingently requires 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.

7. Convertible Preferred Stock

In May 2020, the Company filed an amendment to its certificate of incorporation to authorize 15,313,382 shares of Series D Preferred and 8,973,261 shares of Series D-1 convertible preferred stock ("Series D-1 Preferred"). The Company entered into a stock purchase agreement with certain investors and issued 15,313,382 shares of Series D Preferred for gross proceeds of approximately \$107,500. Upon the achievement of a clinical trial milestone, as defined in the stock purchase agreement, the Series D investors will be obligated to purchase 2,991,087 shares of Series D-1 Preferred for gross proceeds of approximately \$35,833. In addition, the Series D investors will have the right to purchase up to 5,982,174 shares of Series D-1 Preferred ("Additional Series D-1 Preferred") at a price of \$11.98 per share following achievement of the clinical development milestone discussed above and the receipt of certain preclinical data as defined in the stock purchase agreement. Unless previously exercised, the option to purchase the Additional Series D-1 Preferred will terminate (i) eight days after the filing of a registration statement on Form S-1 for the IPO or (ii) in the event that the clinical development milestone discussed above occurs after the filing of a registration statement on a Form S-1 for the IPO and prior to the consummation of the Company's IPO, upon the consummation of the Company's IPO. The Company concluded that the tranche features are not freestanding financing instruments as the right to purchase the future tranches are not legally detachable from the shares of Series D Preferred Stock. Additionally, the Company concluded that no beneficial conversion features were present at initial issuance.

[Table of Contents](#)

As of June 30, 2020, the Company had 57,932,090 shares of convertible preferred stock, or Convertible Preferred Stock, authorized, of which 20,000,000 shares are designated as Series A convertible preferred stock, or Series A Preferred; 7,592,830 shares are designated as Series B convertible preferred stock, or Series B Preferred; 6,052,617 shares are designated as Series C convertible preferred stock, or Series C Preferred; 15,313,382 shares are designated as Series D convertible preferred stock, or Series D Preferred; and 8,973,261 shares are designated as Series D-1 convertible preferred stock, or Series D-1 Preferred. The Company's Series A Preferred, Series B Preferred, Series C Preferred and Series D Preferred were issued at \$1.00, \$3.03, \$4.56 and \$7.02 per share, respectively.

The following table summarizes the Company's outstanding Convertible Preferred Stock:

				June 30, 2020	
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred	20,000,000	20,000,000	\$ 19,136	\$ 20,000	20,000,000
Series B Preferred	7,592,830	7,592,830	22,619	23,006	7,592,830
Series C Preferred	6,052,617	6,052,617	27,359	27,600	6,052,617
Series D Preferred	15,313,382	15,313,382	106,631	107,500	15,313,382
Series D-1 Preferred	8,973,261	—	—	—	—
	<u>57,932,090</u>	<u>48,958,829</u>	<u>\$ 175,745</u>	<u>\$ 178,106</u>	<u>48,958,829</u>

The Company classifies Convertible Preferred Stock outside of stockholders' deficit because the shares contain deemed liquidation rights in the event of a merger, consolidation, or reorganization involving the Company or a subsidiary or upon the sale, lease, transfer, exclusive license or other disposition by the Company or a subsidiary of all or substantially all assets of the Company that could trigger a distribution of cash or assets and therefore a contingent redemption feature not solely within the Company's control.

The rights and preferences of Convertible Preferred Stock are described below:

Voting

Holders of the preferred stock are entitled to vote, together with the holders of common stock, on all matters as to which holders of common stock are entitled to vote, except with respect to matters which Delaware General Corporation Law, or DGCL, or the certificate of incorporation requires a vote by a separate class. Each holder of Convertible Preferred Stock is entitled to one vote for each share of common stock into which the Convertible Preferred Stock is convertible at the time of such vote.

Certain actions specified in the certificate of incorporation require the affirmative vote of Requisite Preferred Holders, which are the holders of a majority of the Series B Preferred, Series C Preferred and Series D Preferred voting together as a single class, while other actions require: (i) the affirmative vote of holders of greater than 50% of Series D Preferred voting as a separate class; (ii) the affirmative vote of holders of at least 57% of Series C Preferred voting as a separate class; (iii) the affirmative vote of holders of at least 67% of the Series B Preferred voting as a separate class; or (iv) the affirmative vote of holders of a majority of the outstanding Convertible Preferred Stock voting as a single class.

At any time when an aggregate of 15,000,000 shares of Convertible Preferred Stock are outstanding, the affirmative vote of the Requisite Preferred Holders is required to (i) purchase, redeem or pay or declare any dividend or make any distribution on any class of stock other than certain specified transactions; or (ii) create or authorize the creation of any class or series of capital stock unless the new class ranks junior to the Convertible Preferred Stock.

Table of Contents

At any time when at least 3,800,000 shares of Series B Preferred are outstanding, the affirmative vote of the holders of at least 67% of the Series B Preferred is required to: (i) amend, alter or repeal the certificate of incorporation or bylaws in any way that adversely affects the powers, preferences or rights of the holders of Series B Preferred; or (ii) increase or decrease the authorized number of shares of Series B Preferred.

At any time when at least 2,200,000 shares of Series C Preferred are outstanding, the affirmative vote of the holders of at least 57% of the Series C Preferred is required to: (i) amend, alter or repeal the certificate of incorporation or bylaws in any way that adversely affects the powers, preferences or rights of the holders of Series C preferred; or (ii) increase or decrease the authorized number of shares of Series C Preferred.

At any time when at least 6,500,000 shares of Series D Preferred are outstanding, the affirmative vote of the holders of at least 50% of the Series D Preferred is required to: (i) amend, alter or repeal the certificate of incorporation or bylaws in any way that adversely affects the powers, preferences or rights of the holders of Series D preferred; (ii) purchase, redeem or pay or declare any dividend or make any distribution on any class of stock other than certain specified transactions; (iii) increase or decrease the authorized number of shares of Series D Preferred; or (iv) approve any liquidation event in which a holder of Series D Preferred would receive less than \$14.04 per share in connection with such event.

As long as at least 15,000,000 shares of Convertible Preferred Stock are outstanding, the affirmative vote of the Requisite Preferred Holders, which are the holders of a majority of the outstanding Convertible Preferred Stock, voting as a single class, is required to affect any liquidation, dissolution, or winding up of the business and affairs of the Company.

The holders of Series A Preferred, Series B Preferred, Series C Preferred and Series D Preferred, voting respectively as separate classes, each have the right to elect a director to the board of directors. The right to elect such a director shall continue for holders of Series A Preferred for so long as 5,000,000 shares of Series A Preferred are outstanding, for holders of Series B Preferred for so long as 5,000,000 shares of Series B Preferred are outstanding, for holders of Series C Preferred for so long as 2,741,228 shares of Series C Preferred are outstanding and for holders of Series D Preferred for so long as 7,000,000 shares of Series D Preferred are outstanding. The remainder of the board of directors, excluding one director that may be elected by holders of common stock voting as a separate class, is elected by the holders of the Convertible Preferred Stock voting together with holders of the common stock as a single class and otherwise in accordance with the stockholders' agreement.

Dividends

Holders of shares of Convertible Preferred Stock are entitled to dividends only if, when and as declared by the board of directors. The Company is prohibited from declaring, paying or setting aside any dividends unless the holders of the then outstanding Convertible Preferred Stock receive first, or simultaneously, in the case of a dividend on common stock, on a *pari passu* basis, a dividend in an amount that is at least equal to the amount that would have been received by the holders of the Convertible Preferred Stock had all the Convertible Preferred Stock been converted to common stock. As of June 30, 2020, no dividends have been declared or paid on the Convertible Preferred Stock.

Liquidation Preference

In the event of any liquidation, dissolution, winding up of the affairs or deemed liquidation event of the Company, the holders of Series D Preferred are entitled to receive in preference to the holders of Series C Preferred, an amount equal to the greater of (1) the original purchase price of the Series D Preferred plus all declared but unpaid dividends, or (2) such amount per share of Series D Preferred payable as if converted into common stock. After the preferential payment to the Series D Preferred, the holders of Series C Preferred are entitled to receive in preference to the holders of Series A Preferred and Series B Preferred and the common

[Table of Contents](#)

stock, an amount equal to the greater of (1) the original purchase price of the Series C Preferred plus all declared but unpaid dividends, or (2) such amount per share of Series C Preferred payable as if converted into common stock. After the preferential payment to holders of the Series C Preferred, the holders of Series A Preferred and Series B Preferred, on a *pari passu* basis and prior and in preference to the holders of common stock, are entitled to receive an amount equal to the greater of (1) the original purchase price of the applicable series of preferred stock plus all declared but unpaid dividends, or (2) such amount per share of preferred stock payable as if converted into common stock. After the preferential distributions are made to the holders of Convertible Preferred Stock, any remaining assets of the Company will be distributed ratably among the holders of common stock. If the assets or surplus funds to be distributed to the holders of the Convertible Preferred are insufficient to permit the payment to such holders of their full preferential amount, the assets and surplus funds legally available for distribution will be distributed in preferential order, first to the holders of Series D Preferred and next to the holders of Series C Preferred and next to the holders of Series A Preferred and Series B Preferred, in each instance, ratably in proportion to the respective amount that would have been paid if all amounts payable on or with respect to such shares had been paid in full.

In the event of a deemed liquidation event, holders of Convertible Preferred Stock may require the Company to redeem their shares at a price equal to the liquidation amount.

Conversion

Each share of Convertible Preferred Stock is convertible into common stock on a one-for-one basis. Conversion is at the option of the holder of the Convertible Preferred Stock except upon either the closing of a firm commitment underwritten public offering with an equity valuation of at least \$800,000, or upon the written election of the majority of the holders of the Series D Preferred. The conversion price of each of the Series D Preferred, Series C Preferred, Series B Preferred and Series A Preferred at June 30, 2020 is equal to the respective original issue price of each series.

The conversion price is subject to adjustment in accordance with provisions in the certificate of incorporation. Specifically, the holders of Convertible Preferred Stock are entitled to weighted average anti-dilution protection in the event that the Company issues additional securities at a purchase price less than the then effective conversion price.

Registration Rights

The holders of the Convertible Preferred Stock may require the Company in certain circumstances to register for sale the shares of common stock issuable upon conversion of the Convertible Preferred Stock. Such registration would permit the sale of the underlying common stock under the Securities Act of 1933, as amended.

Participation Rights in Future Equity Issuances

All holders of Convertible Preferred Stock have a pro rata right, based on their percentage equity ownership in the Company, to participate, subject only to certain limited exceptions, in subsequent issuances of equity securities of the Company. In addition, should any such holder choose not to purchase its full pro rata share, the remaining holders of Convertible Preferred Stock have the right to purchase the remaining pro rata shares.

Redemption rights

Convertible Preferred Stock has no stated redemption features. However, the Convertible Preferred Stock does contain deemed liquidation rights in the event of a merger, consolidation, or reorganization involving the Company or a subsidiary or on the sale, lease, transfer, exclusive license or other disposition by the Company or

[Table of Contents](#)

a subsidiary of all or substantially all assets of the Company that could trigger a distribution of cash or assets not solely within the Company's control.

8. Common Stock

At June 30, 2020, the authorized capital of the Company included 80,529,575 shares of common stock, of which 10,109,847 shares of common stock were considered issued and outstanding for accounting purposes. As discussed in Note 9, restricted stock awards for an aggregate 200,000 shares are excluded from issued and outstanding shares for accounting purposes. On all matters to be voted upon by the holders of common stock, holders of common stock are entitled to one vote per share. Subject to the rights and preferences applicable to the outstanding shares of Convertible Preferred Stock, the holders of common stock are entitled to receive dividends, when declared by the board, and to share ratably in the Company's assets legally available for distribution to the holders of the Company's stock in the event of liquidation. The holders of common stock have no preemptive, redemption or conversion rights.

The Company had the following reserved shares of common stock:

	<u>June 30,</u> <u>2020</u>
Series A Preferred	20,000,000
Series B Preferred	7,592,830
Series C Preferred	6,052,617
Series D Preferred	15,313,382
Outstanding options	4,186,747
Options available for future grant	3,349,277
	<u>56,494,853</u>

9. Stock-based Compensation

As of June 30, 2020, the Atea Pharmaceuticals 2013 Equity Incentive Plan, as amended, or 2013 Plan, provides for the grant of incentive stock options, non-qualified stock options, restricted common stock awards and other awards for up to 10,979,971 shares of common stock to employees, officers, directors and consultants of the Company.

As of June 30, 2020, options to purchase 4,280,494 shares of common stock and 3,370,000 shares of restricted common stock have been granted under the 2013 Plan, and there were 3,329,477 shares of common stock remaining available for future issuance.

Restricted Common Stock

Restricted stock awards generally include vesting and risk of forfeiture provisions that lapse upon satisfaction of performance conditions or over time periods commencing on the grant date and concluding on the third or fourth anniversary of the grant date. The Company has granted awards totaling 200,000 shares of restricted common stock to a consultant pursuant to the 2013 Plan for consulting and business development services. The consultant paid \$1.21 per share and an aggregate of \$121 for 100,000 of the shares of restricted common stock in 2016 and \$1.24 per share and an aggregate of \$124 for 100,000 of the shares of restricted common stock in 2018. These awards of restricted common stock will vest, and the risk of forfeiture will lapse upon satisfaction of performance conditions detailed in each award. As of June 30, 2020, the performance conditions were not yet probable of being met and, as a result, no compensation expense has yet been recognized for these performance-based awards. The unvested and forfeitable common stock as of June 30, 2020, though legally

[Table of Contents](#)

issued, are excluded from issued and outstanding shares for accounting purposes. Amounts received for the unvested and forfeitable common stock totaling \$245 are included in additional paid-in capital within stockholders' deficit in the consolidated balance sheets. At June 30, 2020, total unrecognized compensation expense related to unvested restricted common stock was \$370.

Stock Options

The following summarizes stock option activity:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2020	3,911,633	\$ 1.50	8.5	\$ 3,915
Granted	293,861	\$ 1.57		
Exercised	(18,747)	\$ 1.43		
Outstanding at June 30, 2020	4,186,747	\$ 1.51	8.1	\$ 10,984
Options exercisable at June 30, 2020	2,361,875	\$ 1.40	7.4	\$ 6,440
Vested or expected to vest at June 30, 2020	4,186,747	\$ 1.51	8.1	\$ 10,984

The aggregate intrinsic value of options granted is calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock.

Option grants generally vest over a service period of three or four years and have a contractual term of ten years. There were no options, forfeited or expired during the six months ended June 30, 2020. As of June 30, 2020, total unrecognized compensation expense related to stock option awards was \$1,845, which amount is being recognized over a remaining weighted average period of 3 years.

Stock-based Compensation Expense

Stock-based compensation expense is classified as follows:

	Six Months Ended June 30,	
	2020	2019
Research and development expense	\$ 157	\$ 125
General and administrative	241	168
Total stock-based compensation expense	\$ 398	\$ 293

10. Net Loss Per Share Attributable to Common Stockholders and Pro Forma Information

Net Loss Per Share Attributable to Common Stockholders

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	Six Months Ended June 30,	
	2020	2019
Convertible Preferred Stock	48,958,829	33,645,447
Stock options to purchase common stock	4,186,747	2,820,000
Non-vested restricted stock	200,000	200,000

Pro Forma Information

The calculation of weighted average shares outstanding for purposes of calculating pro forma net loss per share attributable to common stockholders for the six months ended June 30, 2020 assumes the conversion of 33,645,447 shares of convertible preferred stock into common shares effective January 1, 2020 and 15,313,382 shares of Series D convertible preferred stock into common shares effective May 19, 2020.

11. Income Taxes

The Company incurred net operating losses and recorded a full valuation allowance against net deferred tax assets for all periods presented. Accordingly, the Company has not recorded a provision for federal or state income taxes.

12. Related Party Transactions

For the six months ended June 30, 2020, the Company recorded expense of \$40 for consulting services provided by an entity affiliated with its interim Chief Financial Officer, of which \$19 is included in accounts payable as of June 30, 2020.

Except as disclosed in Note 6 in the notes to the accompanying consolidated financial statements, there were no other material transactions with related parties.

13. Subsequent Events

The holders of the Company's Series D Convertible Preferred Stock had an obligation to purchase 2,991,087 shares of Series D-1 Preferred for gross proceeds of \$35,833 upon the Company's achievement of a clinical trial milestone. In addition, the investors had the right to purchase up to 5,982,174 shares of Series D-1 Preferred ("Additional Series D-1 Preferred") at a price of \$11.98 per share following achievement of the clinical development milestone discussed above and the receipt of certain preclinical data as defined in the stock purchase agreement. In October 2020, the investors exercised their option in full resulting in the issuance of 8,973,261 shares of Series D-1 Preferred stock at a purchase price of \$11.98 for gross proceeds of \$107,500.

In October 2020, the Company entered into a license agreement, ("the License Agreement") with F. Hoffmann-La Roche Ltd and Genentech, Inc. (collectively "Roche"), granting Roche an exclusive license to develop and commercialize certain of the Company's compounds outside of the United States.

Atea is responsible for completing certain ongoing non-clinical and clinical activities at its own expense and supplying certain clinical trial material under the License Agreement. The parties will work collaboratively on a global development plan intended to support regulatory approval and will share joint development costs equally.

[Table of Contents](#)

In connection with the License Agreement, Roche will pay the Company an upfront payment of \$350 million. The License Agreement further provides that Roche is obligated to pay the Company up to \$330 million in the aggregate upon the achievement of certain development or regulatory milestone events; up to \$320 million 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 License Agreement, ranging between low double-digit and mid-twenties, subject to certain adjustments and limitations. Roche has the right to terminate the License Agreement for convenience pursuant to the terms of the agreement.

Through and including November 23, 2020, (the 25th day after the date of this prospectus), all dealers effecting transactions in the Common Stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

12,500,000 Shares



ATEA PHARMACEUTICALS, INC.

Common Stock

PROSPECTUS

J.P. Morgan

Morgan Stanley

Evercore ISI

William Blair

October 29, 2020