
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): May 13, 2021

Atea Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-39661
(Commission
File Number)

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

125 Summer Street
Boston, MA 02110
(Address of principal executive offices) (Zip Code)

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

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	AVIR	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On May 13, 2021, Atea Pharmaceuticals, Inc. (the “Company”) issued a press release announcing financial results for the three months ended March 31, 2021 and other matters described in the press release. A copy of the Company’s press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	<u>Press release, dated May 13, 2021.</u>

SIGNATURES

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

ATEA PHARMACEUTICALS, INC.

Date: May 13, 2021

By: /s/ Andrea Corcoran

Andrea Corcoran

Chief Financial Officer and Executive Vice President, Legal and Secretary

Atea Pharmaceuticals Reports First Quarter 2021 Financial Results and Provides Corporate Update

- *Global Phase 3 MORNINGSKY trial of AT-527 in the outpatient setting recently initiated for the treatment of COVID-19*
- *Enrollment advancing in Phase 1a trial of AT-752; drug candidate being developed for the treatment of dengue fever*

BOSTON, Mass., May 13, 2021 – Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) (“Atea”), a clinical-stage biopharmaceutical company, today reported financial results for the quarter ended March 31, 2021 and provided a corporate update.

“Over the course of a year, we have gone from filing an Investigational New Drug Application for AT-527, an oral direct-acting antiviral for the treatment of COVID-19, to the recent initiation of a global Phase 3 trial in the outpatient setting. Working closely with our strategic partner Roche, this significant milestone represents a major advancement toward our goal of providing an easily administered and widely available oral antiviral to help in the fight against this global pandemic,” said Jean-Pierre Sommadossi, Ph.D., Chief Executive Officer and Founder of Atea.

“In addition to the important work we are doing in COVID-19, we are utilizing the power of our proprietary nucleotide prodrug platform in other infectious diseases. Toward that end, we are very pleased to have initiated our Phase 1a study evaluating the safety, tolerability, and pharmacokinetics of AT-752. We look forward to reporting data from this study in the second half of 2021 and to furthering the development of this novel compound as an oral treatment for dengue fever, which the World Health Organization has called the most important mosquito borne viral disease in the world,” continued Dr. Sommadossi.

AT-527 for the Treatment of COVID-19**Global Phase 3 MORNINGSKY Trial of AT-527 in the Outpatient Setting**

- In April 2021, Atea announced the first patient dosed in a global Phase 3 MORNINGSKY trial evaluating AT-527 in the outpatient setting for the treatment of COVID-19. The trial, which is being conducted in collaboration with Roche, is anticipated to enroll up to 1,400 patients globally. The randomized, double-blind, multi-center, placebo-controlled, outpatient Phase 3 trial will evaluate the efficacy, safety, pharmacokinetics, and antiviral activity of AT-527 in adult and adolescent patients with mild to moderate COVID-19. The primary endpoint, evaluating the efficacy of AT-527 compared with placebo, will measure the time to alleviation or improvement of COVID-19 symptoms.

Phase 2 Trial of AT-527 in the Outpatient Setting

- In February 2021, Atea announced the first patient dosed in a Phase 2 clinical trial evaluating AT-527 in mild or moderate COVID-19 patients in an outpatient setting. The trial, which is being conducted in collaboration with Roche, is anticipated to enroll up to 220 patients globally. The randomized, double-blind, multi-center, placebo-controlled Phase 2 trial will evaluate the antiviral activity, safety, and pharmacokinetics of AT-527 in adult patients with mild or moderate COVID-19 in the outpatient setting. The primary endpoint of this trial is change from baseline in amount of SARS-CoV-2 virus RNA as measured by reverse transcription polymerase chain reaction (RT-PCR) at specified timepoints.

Phase 2 Trial of AT-527 in the Hospitalized Setting

- The ongoing Phase 2 trial in the hospitalized setting is a randomized, double-blind, placebo-controlled, multi-center, global trial of AT-527. This trial is anticipated to enroll approximately 190 hospitalized patients with moderate COVID-19. The primary efficacy endpoint of this trial is the change in level of respiratory insufficiency, and other assessments will include viral kinetics and safety and tolerability of AT-527 at the dose of 550 mg administered twice-daily.

Presentation of AT-527 Phase 1 Results at CROI

- In March 2021, Atea presented favorable results from a Phase 1 study of AT-527 in healthy volunteers at the 28th Annual Conference on Retroviruses and Opportunistic Infections (CROI). The results showed AT-527 was well tolerated with no discontinuations or serious adverse events and no clinically significant changes in vital signs or electrocardiograms were observed. The data also demonstrated that AT-511 (the free base of AT-527) was rapidly absorbed followed by fast and extensive stepwise metabolic activation to the active triphosphate AT-9010, reflected by plasma AT-273. Steady state levels were quickly achieved by the third dose of AT-527. The Phase 1 study results validate the modeling from our preclinical animal models which predict that lung levels should be consistently above the EC₉₀ level of 0.5 uM. Since the respiratory tract is the initiation site of the SARS-CoV-2 replication, these data demonstrate the potential for AT-527 to achieve meaningful drug levels in the lungs.

Overview of AT-527 at ICAR

- In March 2021, at the invitation of the organizers of the 34th International Conference on Antiviral Research (ICAR), Atea presented an overview of AT-527, including the Phase 1 results as well as preclinical data and the underlying mechanistic rationale supporting the use of AT-527 for the treatment of COVID-19.

Publication of Preclinical Data Highlighting Potency of AT-527 Against SARS-CoV-2

- In February 2021, Atea announced the publication of new data showcasing the highly potent *in vitro* antiviral activity of AT-527 against SARS-CoV-2. The new findings were made available in a manuscript published online in *Antimicrobial Agents and Chemotherapy*. These data underscore key mechanistic features enabling AT-527 to inhibit SARS-CoV-2 viral replication and support AT-527's clinical development program.

AT-527 Japan Rights

- In February 2021, Atea announced that Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) in-licensed from Roche the rights to develop and market AT-527 for the treatment of COVID-19 in Japan. The recently initiated global Phase 3 trial evaluating AT-527 in the outpatient setting in adults and adolescent patients with mild to moderate COVID-19 is expected to include patients in Japan.

AT-752 for the Treatment of Dengue Fever

AT-752 Phase 1a Trial

- In March 2021, Atea initiated a randomized, double-blind, placebo-controlled, single- and multiple-ascending dose Phase 1a study that will evaluate the safety, tolerability, and pharmacokinetics of AT-752 in healthy subjects. The Phase 1a study is expected to enroll up to 60 subjects in Australia. The objective of the study is to establish the safety and tolerability of AT-752 and also to support dose selection for future studies of AT-752 as a treatment for dengue fever.

First Quarter 2021 Financial Results

Cash and Cash Equivalents: \$833.8 million at March 31, 2021 compared to \$850.1 million at December 31, 2020.

Revenue: Collaboration revenue for the quarter ended March 31, 2021 in the amount of \$66.0 million was derived from the license agreement Atea entered into with F. Hoffmann-La Roche Ltd. and Genentech, Inc. in October 2020 ("Roche License Agreement"). All amounts recognized as revenue during the quarter ended March 31, 2021 were included in deferred revenue at December 31, 2020.

Research and Development Expenses: Research and development expenses for the quarter ended March 31, 2021 in the amount of \$26.6 million increased by \$23.8 million from \$2.8 million for the quarter ended March 31, 2020. The increase in research and development expenses was primarily due to an increase in external expenses incurred related to the CRO and CMO services in conjunction with the advancement of product candidates for the treatment of COVID-19 and dengue fever, including our share of costs incurred by Roche, and increases in internal spend primarily due to an increase in personnel-related expenses, including salaries and bonuses, benefits and stock-based compensation expense for our research and product development employees and consulting fees and other research and development expenses.

General and Administrative Expenses: General and administrative expenses for the quarter ended March 31, 2021 in the amount of \$8.8 million increased by \$7.6 million from \$1.2 million for the quarter ended March 31, 2020. The increase in general and administrative expenses was primarily due to the expansion of our organization and reflected an increase in payroll and personnel-related expenses, including salaries, benefits and stock-based compensation expense and other general and administrative expenses.

Net income (loss): Net income for the quarter ended March 31, 2021 in the amount of \$30.7 million increased by \$34.7 million from a net loss of \$4.0 million for the quarter ended March 31, 2020. The net income for the quarter ended March 31, 2021 resulted principally from the recognition of collaboration revenue related to the Roche License Agreement in the amount of \$66.0 million, partially offset by the increases in research and development expenses and general and administrative expenses described above.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands, except share and per share amounts)
(Unaudited)

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

Selected Consolidated Balance Sheet Data
(in thousands)

	March 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	\$ 833,751	\$ 850,117
Working capital (1)	\$ 585,867	\$ 547,682
Total assets	\$ 840,649	\$ 863,632
Deferred revenue	\$ 235,382	\$ 301,367
Total stockholders' equity	\$ 586,258	\$ 547,801

(1) The Company defines working capital as current assets less current liabilities. See the Company's condensed consolidated financial statements in its Quarterly Report on Form 10-Q for the three months ended March 31, 2021 for further detail regarding its current assets and liabilities.

Conference Call and Webcast Information

Atea will host a conference call and live audio webcast to discuss the first quarter 2021 financial results and provide a corporate update today at 4:30 p.m. ET. To access the live conference call, please dial (833) 301-1150 (domestic) or (914) 987-7391 (international) at least five minutes prior to the start time and refer to conference ID 8609279.

A live audio webcast of the call and accompanying slide presentation will also be available in the Investors' Events & Presentations section of the Company's website, www.ateapharma.com. An archived webcast will be available on the Atea website approximately two hours after the event.

About the AT-527 COVID-19 Clinical Development Program

AT-527 is an orally administered, direct-acting antiviral agent derived from Atea's nucleotide prodrug platform. AT-527 is currently under evaluation as a treatment for patients with COVID-19. In collaboration with Roche, AT-527 is currently being evaluated in the global Phase 3 MORNINGSKY trial, a global Phase 2 study for hospitalized patients with moderate COVID-19 and a Phase 2 outpatient study in patients with mild or moderate COVID-19.

Direct-acting antivirals, such as AT-527, aim to prevent disease progression by minimizing or eliminating viral replication and thereby reducing the severity of the disease, preventing, or shortening hospitalization, and also potentially preventing transmission of the virus to others. This makes AT-527 well suited for potential use in both pre- and post-exposure prophylactic settings and complementary to vaccines.

About Atea Pharmaceuticals

Atea Pharmaceuticals is a clinical stage biopharmaceutical company focused on discovering, developing and commercializing therapies to address the unmet medical needs of patients with life-threatening viral diseases. Leveraging the Company's deep understanding of antiviral drug development, nucleos(t)ide chemistry, biology, biochemistry and virology, Atea has built a proprietary 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, Atea is 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 (SARS-CoV-2), the virus that causes COVID-19, dengue virus, hepatitis C virus (HCV) and respiratory syncytial virus (RSV). For more information, please visit www.ateapharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding our expectations surrounding the safety, efficacy and demand for our product candidates, in particular AT-527; plans and timing for clinical trials and data; our strategic collaboration with Roche; and our competitive position. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: uncertainty around and costs associated with the development of AT-527 as a potential treatment for COVID-19 and our other product candidates; dependence on management, directors and other key personnel; the impact of the COVID-19 pandemic on our business; our limited operating history and significant losses since inception; our need for substantial additional funding; our ability to use our net operating loss carryforwards; our

dependence on the success of our most advanced product candidates; risks related to the regulatory approval process; risks associated with the clinical development process; risks related to healthcare laws and other legal compliance matters; risks related to potential commercialization; risks related to manufacturing and our dependence on third parties; risks relating to intellectual property; our ability to maintain effective internal control over financial reporting and the significant costs as a result of operating as a public company. These and other important factors discussed under the caption “Risk Factors” in our most recent Quarterly Report on Form 10-Q, and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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