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): November 7, 2024

Atea Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39661**	**46-0574869**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

225 Franklin Street
Suite 2100
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 Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	AVIR	The Nasdaq Global Select Market

Indicate by check mark whether the registrant 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 November 7, 2024 Atea Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three months ended September 30, 2024 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	Press release dated November 7, 2024.
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document

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: November 7, 2024

By: /s/ Andrea Corcoran
Andrea Corcoran
Chief Financial Officer and Executive Vice President, Legal and Secretary

Atea Pharmaceuticals Reports Third Quarter 2024 Financial Results and Provides Business Update

Topline SVR12 Results from Global Phase 2 Hepatitis C Virus (HCV) Study (N=275) Expected Q4'24

New Data Supportive of HCV Combination to be Presented at the American Association for the Study of Liver Diseases' (AASLD's) The Liver Meeting 2024

Pharmacokinetic Data for Bemnifosbuvir to be Presented at American College of Pharmacometrics Meeting

Conference Call at 4:30 pm ET Today

BOSTON, Mass., November 7, 2024 – Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) (Atea or Company), a clinical-stage biopharmaceutical company engaged in the discovery and development of oral antiviral therapeutics for serious viral diseases, today reported financial results for the third quarter ended September 30, 2024 and provided a business update.

"We continue to make significant progress in our HCV program with the combination of bemnifosbuvir and ruzasvir, which has a potential best-in-class profile. In the near term, we look forward to sharing topline results in early December from our Phase 2 combination study and initiating the global Phase 3 program early next year," said Jean-Pierre Sommadossi, PhD, Chief Executive Officer and Founder of Atea Pharmaceuticals. "The unrelenting high rate of new HCV infections underscores the need for new innovative therapies that can address the unmet needs of today's HCV patients, particularly those with substance abuse disorders and comorbidities. The HCV commercial market is expected to remain large, with global net sales exceeding $3 billion, with the US accounting for approximately half of this market. Based on our target profile that is convenient, short treatment duration with a low risk of drug-drug interactions, we are confident that our combination, if approved, has the potential to gain significant market share and could increase the number of patients cured."

Hepatitis C Virus (HCV)

Phase 2 HCV Combination Study: Atea is currently completing a global Phase 2 clinical study evaluating the combination of bemnifosbuvir, a nucleotide analog polymerase inhibitor, and ruzasvir, an NS5A inhibitor, for the treatment of HCV. This study, which has enrolled 275 treatment-naïve patients, both with and without compensated cirrhosis, is designed to evaluate the safety and efficacy of eight weeks of treatment with the combination consisting of once-daily bemnifosbuvir 550 mg and ruzasvir 180 mg. The primary endpoints of the study are safety and sustained virologic response at 12 weeks post-treatment (SVR12) in the per-protocol treatment adherent population. Secondary and other endpoints include SVR12 in the per-protocol population regardless of treatment adherence (efficacy evaluable), virologic failure and resistance. Atea expects to report topline Phase 2 SVR12 results from this study in early December 2024.

At the European Association of the Study of the Liver (EASL) Congress in June 2024, Atea presented clinical data from the lead-in cohort (n=60) of the ongoing Phase 2 study. With an 8-week treatment duration, data from the lead-in cohort of non-cirrhotic patients showed a 97% SVR12 rate in efficacy evaluable patients. Two subjects (GT1b and GT2b) experienced post-treatment relapse or failure. Each of these patients had low plasma drug levels and similar viral mutations at both the baseline and 12-weeks post-treatment timepoint, which indicated that the relapse or failure was due to treatment non-adherence rather than viral resistance. These results also showed a 100% SVR12 rate in participants infected with genotype 3 (n=13), a historically difficult-to-treat genotype of HCV. In the lead-in cohort, the combination regimen was well tolerated, with no drug-related serious adverse events or treatment discontinuations.

Data also presented at EASL included additional preclinical data further demonstrating a high barrier to resistance and favorable pharmacokinetics (PK) for bemnifosbuvir and a low risk of drug-drug interactions for ruzasvir. Atea has previously reported a low risk of drug-drug interactions for bemnifosbuvir.

Atea is currently planning for an End of Phase 2 meeting with the US Food and Drug Administration early in the first quarter of 2025 to support the initiation of the Phase 3 program.

Atea has selected and is manufacturing a fixed dose combination (FDC) tablet for its upcoming Phase 3 program. The FDC tablet reduces the daily pill count from four to two tablets, enhancing patient convenience, with no food effect demonstrated in recent studies.

New Data Presentations at Upcoming Scientific Meetings

At The Liver Meeting 2024, being held from November 15-19, 2024, three posters supportive of the combination of bemnifosbuvir and ruzasvir as a potential treatment for HCV will be presented. The posters detail additional safety and resistance data for bemnifosbuvir and present multiscale modeling data estimating the effectiveness of the combination of bemnifosbuvir and ruzasvir in blocking HCV replication and viral assembly and secretion.

At the American College of Pharmacometrics meeting, being held on November 11, 2024, supportive data from an integrated population PK model that was developed to simultaneously characterize the PK profile of bemnifosbuvir and its metabolites will be presented.

COVID-19

Phase 3 SUNRISE-3 Trial: In September 2024, Atea announced results from the Phase 3 SUNRISE-3 trial, a global, multicenter, randomized, double-blind, placebo-controlled study evaluating bemnifosbuvir in patients with mild to moderate COVID-19. The trial did not meet its primary endpoint of a statistically significant reduction in all-cause hospitalization or death through Day 29. Total enrollment for the monotherapy cohort consisted of 2,221 high-risk patients randomized 1:1 to receive bemnifosbuvir 550 mg twice-daily (BID) or placebo BID for five days. In the trial, bemnifosbuvir was shown to be generally safe and well tolerated.

The evolving nature of COVID-19, including milder disease presentations and a reduction in hospitalizations due to COVID-19 related severe respiratory disease, pose significant challenges in demonstrating a clinical impact with a direct-acting antiviral such as bemnifosbuvir. Given the trial results and the changing landscape of the pandemic, Atea will not pursue a regulatory pathway forward for bemnifosbuvir for COVID-19.

Third Quarter 2024 Financial Results

Cash, Cash Equivalents and Marketable Securities: $482.8 million at September 30, 2024 compared to $502.2 million at June 30, 2024.

Research and Development Expenses: Research and development expenses decreased by $2.0 million from $28.2 million for the three months ended September 30, 2023 to $26.2 million for the three months ended September 30, 2024. The net decrease was primarily driven by lower external spend related to our COVID-19 Phase 3 SUNRISE-3 clinical trial offset by higher spend related to our HCV Phase 2 clinical trial of the combination of bemnifosbuvir and ruzasvir.

General and Administrative Expenses: General and administrative expenses decreased by $1.6 million from $12.6 million for the three months ended September 30, 2023 to $11.0 million for the three months ended September 30, 2024. The net decrease was primarily related to lower professional fees.

Interest Income and Other, Net: Interest income and other, net, decreased by $1.6 million for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, primarily due to lower investment balances.

Income Taxes: We recorded income tax expense of $0.2 million for each of the three months ended September 30, 2024 and 2023.

Condensed Consolidated Statement of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 26,159	$ 28,181	$ 118,430	$ 79,198
General and administrative	11,043	12,604	35,494	38,391
Total operating expenses	37,202	40,785	153,924	117,589
Loss from operations	(37,202)	(40,785)	(153,924)	(117,589)
Interest income and other, net	6,277	7,864	19,782	21,466
Loss before income taxes	(30,925)	(32,921)	(134,142)	(96,123)
Income tax expense	(226)	(221)	(700)	(669)
Net loss	$ (31,151)	$ (33,142)	$ (134,842)	$ (96,792)
Other comprehensive loss				
Unrealized gain (loss) on available-for-sale investments	921	48	434	422
Comprehensive loss	$ (30,230)	$ (33,094)	$ (134,408)	$ (96,370)
Net loss per share - basic and diluted	$ (0.37)	$ (0.40)	$ (1.60)	$ (1.16)
Weighted-average number of common shares - basic and diluted	84,422,000	83,399,769	84,198,117	83,374,328

Selected Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	482,813	578,106
Working capital[(1)]	461,716	558,079
Total assets	490,957	594,968
Total liabilities	32,436	39,776
Total stockholder's equity	458,521	555,192

(1) Atea 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 September 30, 2024 for further detail regarding its current assets and liabilities.

Conference Call and Webcast

Atea will host a conference call and live audio webcast to discuss third quarter 2024 financial results and provide a business update today at 4:30 p.m. ET. To access the live conference call, participants may register here. The live audio webcast of the call will be available under "Events and Presentations" in the Investor Relations section of the Atea Pharmaceuticals website at ir.ateapharma.com. To participate via telephone, please register in advance here. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. While not required, it is recommended that participants join the call ten minutes prior to the scheduled start. An archive of the audio webcast will be available on Atea Pharmaceuticals' website approximately two hours after the conference call and will remain available for at least 90 days following the event.

About Bemnifosbuvir and Ruzasvir for Hepatitis C Virus (HCV)

Bemnifosbuvir has been shown in *in vitro* studies to be approximately 10-fold more active than sofosbuvir (SOF) against a panel of laboratory strains and clinical isolates of HCV GT 1–5. In vitro studies have also demonstrated bemnifosbuvir remained fully active against SOF resistance-associated substitutions (S282T), with up to 58-fold more potency than SOF. The PK profile of bemnifosbuvir supports once-daily dosing for the treatment of HCV. Bemnifosbuvir has been shown to have a low risk for drug-drug interactions. Bemnifosbuvir has been administered to over 2,200 subjects and has been well-tolerated at doses up to 550 mg for durations up to 12 weeks in healthy subjects and patients.

Ruzasvir has demonstrated highly potent and pan-genotypic antiviral activity in preclinical (picomolar range) and clinical studies. Ruzasvir has been administered to over 1,500 HCV-infected patients at daily doses of up to 180 mg for 12 weeks and has demonstrated a favorable safety profile. The PK profile of ruzasvir supports once-daily dosing.

About Atea Pharmaceuticals

Atea is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing oral antiviral therapies to address the unmet medical needs of patients with serious viral infections. Leveraging Atea's deep understanding of antiviral drug development, nucleos(t)ide chemistry, biology, biochemistry and virology, Atea has built a proprietary nucleos(t)ide prodrug platform to develop novel product candidates to treat single stranded ribonucleic acid, or ssRNA, viruses, which are a prevalent cause of serious viral diseases. Atea plans to continue to build its pipeline of antiviral product candidates by augmenting its nucleos(t)ide platform with other classes of antivirals that may be used in combination with its nucleos(t)ide product candidates. Our lead program and current focus is on the development of the combination of bemnifosbuvir, a nucleotide analog polymerase inhibitor and ruzasvir, an NS5A inhibitor, to treat hepatitis C virus. For more information, please visit www.ateapharma.com.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include but are not limited to the anticipated timing for reporting the topline results from Atea's Phase 2 trial of the combination of bemnifosbuvir and ruzasvir for the treatment of HCV, meeting with the FDA, and potential initiation of the HCV Phase 3 program. When used herein, words including "will," "plans", and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon Atea's current expectations and various assumptions. Atea believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Atea may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, dependence on the success of Atea's most advanced product candidates, in particular the combination of bemnifosbuvir and ruzasvir for the treatment of hepatitis C; as well as the other important factors discussed under the caption "Risk Factors" in Atea's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC's website at www.sec.gov. These and other important factors 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 Atea may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing Atea's views as of any date subsequent to the date of this press release.

Contacts

Jonae Barnes
SVP, Investor Relations and Corporate Communications
617-818-2985
barnes.jonae@ateapharma.com

Will O'Connor
Precision AQ
212-362-1200
will.oconnor@precisionaq.com