

**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 14, 2022

ALPINE IMMUNE SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37449
(Commission
File Number)

20-8969493
(IRS Employer
Identification No.)

188 East Blaine Street, Suite 200
Seattle, Washington 98102
(Address of principal executive offices, including zip code)

(206) 788-4545

(Registrant's telephone number, including 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	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ALPN	The Nasdaq Stock Market LLC

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 14, 2022, Alpine Immune Sciences, Inc. issued a press release reporting its financial results for the three and nine months ended September 30, 2022. A copy of the press release is furnished herewith as Exhibit 99.1.

Item 7.01 Regulation FD Disclosure.

The Company announces material information to the public through a variety of means, including filings with the Securities and Exchange Commission, press releases, public conference calls, the Company's website (www.alpineimmunesciences.com), its investor relations website (ir.alpineimmunesciences.com), and its news site (ir.alpineimmunesciences.com/newsreleases). The Company uses these channels, as well as social media, including its Twitter account (@AlpineImmuneSci) and LinkedIn account (www.linkedin.com/company/alpine-immune-sciences), to communicate with investors and the public about the Company, its product candidates, and other matters. Therefore, the Company encourages investors, the media, and others interested in the Company to review the information it makes public in these locations, as such information could be deemed to be material information.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 14, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The information furnished in this Current Report under Items 2.02 and 7.01 and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Alpine Immune Sciences Provides Corporate Update and Reports Third Quarter 2022 Financial Results

SEATTLE, Washington, - November 14, 2022 - Alpine Immune Sciences, Inc. (NASDAQ: ALPN), a leading clinical-stage immunotherapy company focused on developing innovative treatments for autoimmune and inflammatory diseases, today provided a corporate update and reported financial results for the third quarter ended September 30, 2022.

“During our inaugural R&D Day and throughout subsequent scientific meetings this fall, we have shared promising nonclinical and clinical data that supports the best-in-class potential for our lead program ALPN-303 in multiple autoimmune and inflammatory indications. In particular, recent data from healthy volunteers presented at ASN’s Kidney Week demonstrated dose-dependent reductions in Gd-IgA1, a key effector molecule and clinical biomarker of disease progress in IgAN, and the first clinical disease-related biomarker data with ALPN-303,” said Mitchell H. Gold, MD, Executive Chairman and Chief Executive Officer of Alpine. “To further accelerate development of this promising program in multiple indications, we completed a successful \$113 million follow-on offering with top-tier investors in October, extending our cash runway through the end of 2025. We now look forward to beginning a broad development plan for ALPN-303, including a phase 2 study in systemic lupus erythematosus (SLE). In addition, we are particularly excited to begin open-label basket studies in glomerulonephritis and autoimmune cytopenias as they should provide a rapid assessment in multiple diseases and may potentially enable multiple accelerated development paths.”

Gold continued, “as previously announced, we have voluntarily terminated enrollment in the davocetcept (ALPN-202) clinical studies. We would like to thank the patients and investigators who participated in the NEON studies. We remain focused on using our resources to further advance ALPN-303, as well as acazicolcept (ALPN-101) in SLE in collaboration with AbbVie”.

Third Quarter 2022 and Recent Pipeline and Corporate Updates

ALPN-303

- During the September R&D Day, the Company shared updated preliminary data from the phase 1 study (RUBY-1) of ALPN-303 in healthy volunteers and presented a broad development plan, including a proof-of-concept phase 2 study in SLE and basket studies in renal and hematologic autoimmune diseases, with initial clinical data from the basket studies expected in late 2023.
- At the American Society of Nephrology: Kidney Week Meeting, updated clinical data were presented in a poster titled, “Phase 1 Study in Healthy Adults of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ALPN-303, a Dual BAFF/APRIL Antagonist for the Treatment of Autoimmune Glomerulonephritides (GN)”.
 - The data demonstrate that ALPN-303 continues to be well tolerated as single intravenous or subcutaneous doses of up to 960 mg and exhibits dose-related pharmacokinetic and on-target pharmacodynamic effects.
 - ALPN-303 maintains target coverage of free APRIL for 2-3 and ≥ 4 weeks with 80 and 240 mg, respectively, corresponding to reductions in serum Ig and antibody-secreting cells (CD38hi plasmablasts/plasma cells).
 - ALPN-303 dose-dependently reduces serum galactose-deficient IgA1 (Gd-IgA1), a critical molecule implicated in the pathogenesis of IgA nephropathy (IgAN).
 - These data support dose regimens of 80-240 mg SC every 4 weeks in future GN studies.
- The Company also presented clinical data from the RUBY-1 study of healthy vs at the recent American College of Rheumatology in a poster titled, “A Randomized Placebo-Controlled Phase 1 Study in Healthy Adult Volunteers of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of ALPN-303, a Potent Dual BAFF/APRIL Antagonist for the Treatment of Systemic Lupus Erythematosus and Other Autoantibody-Associated Diseases”.
- Additional updates will be presented at the American Society of Hematology Conference in December.

Corporate

- The Company ended the third quarter with \$277.1 million in cash, cash equivalents, restricted cash, and investments, following the successful completion of a \$100.0 million underwritten public offering where we sold 13.6 million shares of our common stock with net proceeds of approximately \$93.5 million, after deducting underwriting, commissions and estimated offering expenses.
- An additional 1.9 million shares of our common stock were sold pursuant to the underwriters’ partial exercise of their over-allotment option, with net proceeds of \$13.1 million received upon closing on October 4, 2022.

- The financing brings our pro-forma cash and investments balance to \$290.2 million as of September 30, 2022, which should be sufficient to fund our planned operations through 2025.
- On October 24, the Company announced that it had voluntarily terminated enrollment in the NEON studies of davoceticept as a monotherapy and in combination with pembrolizumab.

Third Quarter 2022 Financial Results

As of September 30, 2022, Alpine's cash, cash equivalents, restricted cash and investments totaled \$277.1 million. The Company recorded net losses of \$13.3 million and \$13.5 million for the quarters ended September 30, 2022 and 2021, respectively.

Collaboration revenue for the third quarter ended September 30, 2022 was \$8.4 million compared to \$8.5 million for the third quarter ended September 30, 2021. The 2022 amounts were primarily attributable to revenue recognized under the Company's AbbVie and Horizon collaborations, while 2021 revenue recognized solely related to the AbbVie collaboration.

Research and development expenses for the third quarter ended September 30, 2022 were \$17.6 million compared to \$18.3 million for the third quarter ended September 30, 2021. The decrease was primarily attributable to decreased clinical development activities offset by higher personnel-related expenses due to increased headcount.

General and administrative expenses for the third quarter ended September 30, 2022 were \$4.6 million compared to \$3.5 million for the third quarter ended September 30, 2021. The increase was primarily attributable to increases in personnel costs.

About ALPN-303 and the RUBY-1 Study

ALPN-303 is a dual antagonist of the BAFF (B cell activating factor) and APRIL (a proliferation inducing ligand) cytokines, which play key roles in the activation and survival of B cells. Based upon an engineered TACI (transmembrane activator and CAML interactor) domain, ALPN-303 exhibits greater potency in preclinical studies versus wild-type TACI-based comparators, as well as other inhibitors of BAFF and/or APRIL alone. ALPN-303 is in development for multiple B cell and/or autoantibody-related diseases, such as systemic lupus erythematosus, glomerulonephritides, and autoimmune cytopenias.

RUBY-1 (NCT05034484) is a phase 1, randomized, placebo-controlled study in healthy adult volunteers designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of single doses of intravenously and subcutaneously administered ALPN-303. Initial data show ALPN-303 to be well tolerated up to 960 mg with dose-dependent pharmacokinetics and reductions in circulating immunoglobulins and antibody-secreting cells, supporting the use of a once every four-week dose regimen for subsequent studies.

About Alpine Immune Sciences

Alpine Immune Sciences is committed to leading a new wave of immune therapeutics. With world-class research and development capabilities, a highly productive scientific platform, and a proven management team, Alpine is seeking to create first- or best-in-class multifunctional immunotherapies via unique protein engineering technologies to improve patients' lives. Alpine has entered into strategic collaborations with leading global biopharmaceutical companies and has a diverse pipeline of clinical and preclinical candidates in development. For more information, visit www.alpineimmunesciences.com. Follow @AlpineImmuneSci on Twitter and LinkedIn.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and include statements regarding our platform technology and potential therapies; the potential efficacy, safety profile, future development plans, addressable market, regulatory success, and commercial potential of our product candidates; and the timing of our public presentations and potential publication of future clinical data. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions and include words such as "may," "will," "should," "would," "expect," "plan," "intend," and other similar expressions, among others. These forward-looking statements are based on current assumptions that involve risks, uncertainties, and other factors that may cause actual results, events, or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: clinical trials may not demonstrate safety and efficacy of any of our product candidates; our ongoing discovery and preclinical efforts may not yield additional product candidates; our discovery-stage and preclinical programs may not advance into the clinic or result in approved products; any of our product candidates may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; we may not

achieve additional milestones in our proprietary or partnered programs; the impact of competition; adverse conditions in the general domestic and global economic markets; the impact of the COVID-19 pandemic on our business, research and clinical development plans and timelines and results of operations, including the impact on our clinical trial sites, collaborators, and contractors who act for or on our behalf, may be more severe and prolonged than currently anticipated; as well as the other risks identified in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and we undertake no obligation to update forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

“NEON-1,” “NEON-2,” “Synergy,” and the Alpine logo are registered trademarks or trademarks of Alpine Immune Sciences, Inc. in various jurisdictions.

ALPN-202, NEON-2 study in collaboration with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA

Alpine Immune Sciences, Inc.

Selected Consolidated Balance Sheet Data

(In thousands)

	September 30, 2022	December 31, 2021
	(unaudited)	
Cash and cash equivalents	\$ 126,625	\$ 67,907
Short-term investments	122,237	94,396
Total current assets	253,239	192,013
Long-term investments	28,016	52,866
Total assets	291,599	255,900
Total current liabilities	68,459	69,778
Total stockholders' equity	182,009	120,903
Total liabilities and stockholders' equity	291,599	255,900

Consolidated Statement of Operations and Comprehensive Income (Loss) Data

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(unaudited)			
Collaboration revenue	\$ 8,367	\$ 8,516	\$ 27,288	\$ 18,913
Operating expenses:				
Research and development	17,589	18,309	51,487	43,380
General and administrative	4,610	3,470	13,579	10,016
Total operating expenses	22,199	21,779	65,066	53,396
Loss from operations	(13,832)	(13,263)	(37,778)	(34,483)
Other income (expense):				
Interest expense	(105)	(203)	(389)	(638)
Interest income	664	52	1,123	166
Other expense	—	—	(72)	—
Loss before taxes	(13,273)	(13,414)	(37,116)	(34,955)
Income tax expense	—	(80)	(1,782)	(211)
Net loss	\$ (13,273)	\$ (13,494)	\$ (38,898)	\$ (35,166)
Comprehensive income (loss):				
Unrealized loss on investments	(307)	(17)	(1,385)	(1)
Unrealized gain (loss) on foreign currency translation	7	(13)	(11)	(37)
Comprehensive loss	\$ (13,573)	\$ (13,524)	\$ (40,294)	\$ (35,204)
Weighted-average shares used to compute basic and diluted net loss per share	31,574,358	24,724,442	31,559,886	24,169,993
Basic and diluted net loss per share	\$ (0.42)	\$ (0.55)	\$ (1.23)	\$ (1.45)

Source: Alpine Immune Sciences, Inc.**Contacts:**

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