

**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): March 17, 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 March 17, 2022, Alpine Immune Sciences, Inc. issued a press release reporting its financial results for the three months and year ended December 31, 2021. 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 March 17, 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 Fourth Quarter and Full Year 2021 Financial Results

- Execution across three clinical-stage programs and addition of \$176 million in committed cash in 2021 from partnerships and financing to further advance pipeline -
- Davoceticept monotherapy dose escalation data to be presented at 2022 AACR Annual Meeting -
- ALPN-303 phase 1 ongoing; data expected mid-2022 -

SEATTLE, Wash., - March 17, 2022 - Alpine Immune Sciences, Inc. (NASDAQ: ALPN), a leading clinical-stage immunotherapy company focused on developing innovative treatments for cancer and autoimmune and inflammatory diseases, today provided a corporate update and reported financial results for the fourth quarter and year ended December 31, 2021.

“2021 was a period of significant growth at Alpine with the advancement of all three of our clinical programs into significant stages of development,” said Mitchell H. Gold, MD, Executive Chairman and Chief Executive Officer of Alpine. “As a result we secured \$176 million in additional capital through a PIPE financing, the achievement of milestones as part of our AbbVie collaboration and an upfront payment from our recently announced discovery partnership with Horizon Therapeutics.”

Dr. Gold added: “2022 looks to be a transformative year for Alpine with several important readouts anticipated across our programs, including the completion of dose escalation for davoceticept monotherapy and initiation of expansion cohorts; as well as the completion of the phase 1 healthy volunteer study for ALPN-303 and initiation of one or more patient-based studies in autoantibody-related diseases by the end of the year.”

Full Year 2021 and Recent Clinical and Corporate Updates

- **Davoceticept (ALPN-202): Conditional CD28 costimulator and dual checkpoint inhibitor**
 - Davoceticept monotherapy dose escalation data (NEON-1) will be presented in an oral presentation at the 2022 American Association for Cancer Research (AACR) Annual Meeting on April 12, 2022. Initial findings of davoceticept’s tolerability and clinical activity were previously reported in an oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting.
 - NEON-1 monotherapy expansion cohorts in patients with cutaneous melanoma and PD-L1+ tumors projected to be initiated in the first half of 2022.
 - Announced partial clinical hold on the NEON-2 trial combining davoceticept with pembrolizumab. Participants previously enrolled can continue to receive davoceticept and pembrolizumab; the NEON-1 monotherapy trial was not affected.
- **ALPN-303: Dual APRIL/BAFF inhibitor**
 - Began a first-in-human, phase 1 study of ALPN-303 in healthy volunteers in the fourth quarter of 2021; initial safety, pharmacokinetic, and pharmacodynamic findings anticipated by mid-2022.
 - Preclinical data, highlighting the differentiation and potential best-in-class profile of ALPN-303, were presented in two oral presentations at the European Alliance of Associations for Rheumatology and American College of Rheumatology Convergence 2021 meetings.
 - Plan to initiate studies in systemic lupus erythematosus (SLE) and potentially additional autoantibody-related diseases in the second half of 2022.
- **Acazicolcept (ALPN-101): Dual CD28/ICOS inhibitor**
 - Received \$45 million in pre-option exercise development milestones as part of the Option and License Agreement with AbbVie, bringing total upfront and milestone payments received through December 31, 2021, to \$105 million.
 - Continue to enroll Synergy, a phase 2 trial of acazicolcept in patients with SLE.

- With collaborators at the French National Institute of Health and Medical Research (INSERM), demonstrated that acazicolcept decreased manifestations of systemic sclerosis in preclinical mouse models (Arthritis Res Ther 24: 13, 2022)

- **General Corporate**

- Announced an exclusive license and collaboration agreement with Horizon Therapeutics plc for the development and commercialization of up to four preclinical candidates generated from Alpine's unique discovery platform, which included \$40 million in upfront payments (\$25 million cash and \$15 million equity investment at a 25% premium to the 30-day volume-weighted average share price) and eligibility to receive up to \$1.5 billion in total, through future milestone-based payments.
- Raised \$91 million in a private placement, led by Frazier Life Sciences Public Fund with participation from Decheng Capital, BVF Partners, TCG X, Avidity Partners, OrbiMed, Omega Fund, and Logos Capital, among others.

Fourth Quarter and Full Year 2021 Financial Results

As of December 31, 2021, we had cash, cash equivalents, and investments totaling \$215.4 million. Net cash used in operating activities for the year ended December 31, 2021 was \$15.2 million compared to net cash provided by operating activities of \$30.1 million for the year ended December 31, 2020. The Company recorded net losses of \$50.3 million and \$27.9 million for the years ended December 31, 2021 and 2020, respectively.

Collaboration revenue for the fourth quarter ended December 31, 2021 was \$4.5 million compared to \$5.6 million for the fourth quarter ended December 31, 2020. Collaboration revenue for the year ended December 31, 2021 was \$23.4 million compared to \$9.3 million for the year ended December 31, 2020. The amounts were primarily attributable to the revenue recognized under our AbbVie Agreement.

Research and development expenses for the fourth quarter ended December 31, 2021 were \$15.4 million compared to \$9.1 million for the fourth quarter ended December 31, 2020. Research and development expenses for the year ended December 31, 2021 were \$58.7 million compared to \$27.2 million for the year ended December 31, 2020. The increases were primarily attributable to our Synergy and NEON studies, contract manufacturing and process development of our product candidates primarily for acazicolcept and ALPN-303, increased personnel costs and other direct research activities.

General and administrative expenses for the fourth quarter ended December 31, 2021 were \$4.5 million compared to \$3.0 million for the fourth quarter ended December 31, 2020. General and administrative expenses for the year ended December 31, 2021 were \$14.6 million compared to \$10.9 million for the year ended December 31, 2020. The increase was primarily attributable to increases in professional and legal services and personnel costs.

The Company expects that its current cash resources, combined with the \$25 million up-front payment received from Horizon in January 2022 and the potential \$30 million in pre-option exercise milestones payable under its option and license agreement with AbbVie, for the development and commercialization of acazicolcept, will be sufficient to fund its planned operations into 2024.

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 timing of and results from clinical trials and preclinical development activities; clinical and regulatory objectives and the timing thereof; expectations regarding the sufficiency of cash and potential payments to us pursuant to our option and license

agreement with AbbVie to fund our planned operations into 2024; the potential efficacy, safety profile, future development plans, addressable market, regulatory success, and commercial potential of our product candidates; our ability to achieve additional milestones in our collaborations; the progress and potential of our other ongoing development programs; the timing of our public presentations and potential publication of future clinical data; the efficacy of our clinical trial designs; anticipated enrollment in our clinical trials and the timing thereof; expectations regarding our ongoing collaborations; and our ability to successfully develop and achieve milestones in our development programs. 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; efforts to have the partial clinical hold on our NEON-2 trial lifted may be prolonged or ultimately unsuccessful; 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 is being conducted in collaboration with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA

Source: Alpine Immune Sciences, Inc.

Alpine Immune Sciences, Inc.

Selected Consolidated Balance Sheet Data

(In thousands)

	December 31, 2021 (unaudited)	December 31, 2020
Cash and cash equivalents	\$ 67,907	\$ 34,959
Short-term investments	94,396	70,622
Total current assets	192,013	107,101
Long-term investments	52,866	25,549
Total assets	255,900	144,090
Total current liabilities	69,778	41,167
Total stockholders' equity	120,903	62,158
Total liabilities and stockholders' equity	255,900	144,090

Consolidated Statement of Operations and Comprehensive Income (Loss) Data

(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
	(unaudited)			
Collaboration revenue	\$ 4,530	\$ 5,643	\$ 23,443	\$ 9,335
Operating expenses:				
Research and development	15,362	9,055	58,742	27,185
General and administrative	4,544	3,049	14,560	10,899
Total operating expenses	19,906	12,104	73,302	38,084
Loss from operations	(15,376)	(6,461)	(49,859)	(28,749)
Other income (expense):				
Interest expense	(178)	(215)	(816)	(775)
Interest income	93	43	259	245
Other (expense) income	(4)	291	(4)	1,333
Loss before taxes	(15,465)	(6,342)	(50,420)	(27,946)
Income tax (expense) benefit	298	—	87	6
Net loss	\$ (15,167)	\$ (6,342)	\$ (50,333)	\$ (27,940)
Comprehensive income (loss):				
Unrealized (loss) gain on investments	(237)	1	(238)	(15)
Unrealized (loss) gain on foreign currency translation	(51)	93	(88)	58
Comprehensive loss	\$ (15,455)	\$ (6,248)	\$ (50,659)	\$ (27,897)
Weighted-average shares used to compute basic and diluted net loss per share	29,354,961	23,803,183	25,476,889	20,826,466
Basic and diluted net loss per share	\$ (0.52)	\$ (0.27)	\$ (1.98)	\$ (1.34)

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