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 24, 2022

ALPINE IMMUNE SCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37449**	**20-8969493**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 8.01. Other Events.

On May 24, 2022, Alpine Immune Sciences, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has removed the partial clinical hold placed on the Company's NEON-2 trial evaluating davoceticept (ALPN-202). A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated May 24, 2022
104	Cover Page Interactive Data File (formatted in 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.

Date: May 24, 2022

ALPINE IMMUNE SCIENCES, INC.

By: /s/ Paul Rickey
Name: Paul Rickey
Title: Senior Vice President and Chief Financial Officer

FDA Removes Partial Clinical Hold on NEON-2 Clinical Trial of Davoceticept (ALPN-202) in Combination with Pembrolizumab

SEATTLE, Wash., - May 24, 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 announced that the U.S. Food and Drug Administration (FDA) has removed the partial clinical hold placed on its NEON-2 trial evaluating davoceticept (ALPN-202), a first-in-class conditional CD28 costimulator and dual checkpoint inhibitor, in combination with pembrolizumab in adults with advanced malignancies.

The FDA removed the hold after review of the Company's Complete Response, which included a comprehensive review of the davoceticept safety database, as well as a revised investigator brochure and study protocol. As previously disclosed, under the terms of the hold, previously enrolled participants continued to receive study drug, but no new participants could be enrolled until the partial clinical hold was removed. The ongoing NEON-1 study was not subject to the hold.

About Davoceticept (ALPN-202)

Davoceticept (ALPN-202) is a first-in-class, conditional CD28 costimulator and dual checkpoint inhibitor intended for the treatment of cancer. Preclinical studies of davoceticept have successfully demonstrated superior efficacy in tumor models compared to checkpoint inhibition alone. NEON-1 (NCT04186637), a Phase 1 monotherapy dose escalation and expansion trial in patients with advanced malignancies, has completed dose escalation and is currently enrolling its expansion cohorts. NEON-2 (NCT04920383), a combination study of davoceticept (ALPN-202) and pembrolizumab, was initiated in June 2021.

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; the potential efficacy, safety profile, future development plans, addressable market, regulatory success, and commercial potential of our product candidates; the efficacy of our clinical trial designs; anticipated enrollment in our clinical trials and the timing thereof; 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; 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.

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.

Contacts:
Alex Sharif
Director, Investor Relations and Corporate Development
Alpine Immune Sciences, Inc.
206.788.4545
ir@alpineimmunesciences.com

Kelli Perkins (Media)
Red House
310.625.3248
kelli@redhousecomms.com