

**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 14, 2020

ALPINE IMMUNE SCIENCES, INC.
(Exact Name of Registrant as Specified in 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, WA 98102
(Address of principal executive offices, and ZIP code)

Registrant's telephone number including area code: (206) 788-4545
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 May 14, 2020, Alpine Immune Sciences, Inc. issued a press release reporting its financial results for the first quarter ended March 31, 2020. A copy of the press release is furnished herewith as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 14, 2020.

The information furnished in this Current Report under Item 2.02 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 Reports First Quarter 2020 Financial Results and Provides Company Update

- Granted FDA Orphan Drug Designations for ALPN-101 in Acute GVHD -

- BALANCE and NEON-1 Trials Open for Enrollment -

SEATTLE, May 14, 2020-- Alpine Immune Sciences, Inc. (NASDAQ:ALPN), a leading clinical-stage immunotherapy company focused on developing innovative treatments for cancer and autoimmune/inflammatory diseases, today provided a corporate update and reported financial results for the first quarter ended March 31, 2020.

First Quarter 2020 Highlights and Subsequent Updates:

- **The U.S. FDA Granted Orphan Drug Designations for ALPN-101 in the Prevention and Treatment of Acute Graft Versus Host Disease.** In March, the United States Food and Drug Administration (FDA) granted two orphan drug designations for ALPN-101, our first-in-class inhibitor of the CD28 and ICOS inflammation pathways, for the prevention of, and for the treatment of, acute GVHD.
- **ALPN-202 Study Design Presented at AACR.** In April, Alpine presented the design of NEON-1, the first-in-human study of ALPN-202, our first-in-class clinical stage conditional CD28 costimulator and dual checkpoint inhibitor, at the American Association of Cancer Research (AACR) Virtual Annual Meeting I, in the Phase I Trials in Progress Virtual Poster Session.
- **ALPN-101 Preclinical Data in Inflammatory Bowel Disease (IBD) Presented at 2020 Crohn's & Colitis Congress and Digestive Disease Week 2020.** ALPN-101 modulated inflammatory cytokines *in vitro* from human IBD peripheral blood mononuclear cells (PBMC) more potently than CD28 or ICOS single-pathway inhibitors and significantly reduced disease activity *in vivo* in the CD4⁺CD45RB^{hi} T cell transfer mouse colitis model.
- **ALPN-101 and ALPN-202 Clinical Trials Ongoing.** A phase 1b/2 trial of ALPN-101 in acute GVHD (BALANCE, NCT04227938) has been initiated. The NEON-1 trial of ALPN-202 (NCT04186637) is open for enrollment.

“The first quarter was a highly productive one, with now two open clinical studies for both our lead product candidates,” said Mitchell H. Gold, M.D., Executive Chairman and Chief Executive Officer of Alpine. “We were gratified to receive orphan drug designations for ALPN-101 in acute GVHD, where current standard therapies remain inadequate to prevent or control the disease. We also reiterate our excitement over ALPN-202, which is now poised clinically to address a potential key mechanism accounting for checkpoint inhibitor resistance.”

First Quarter 2020 Financial Results

- As of March 31, 2020, Alpine had cash, cash equivalents, restricted cash, and short-term investments totaling \$36.1 million. Net cash used in operating activities for the first quarter ended March 31, 2020 was \$9.7 million compared to \$11.2 million for the first quarter ended March 31, 2019. Alpine recorded a net loss of \$5.5 million and \$12.4 million for the first quarters ended March 31, 2020 and 2019, respectively.
- Research and development expenses for the first quarter ended March 31, 2020 were \$4.9 million compared to \$10.4 million for the first quarter ended March 31, 2019.
- General and administrative expenses for the first quarter ended March 31, 2020 were \$1.8 million compared to \$2.3 million for the first quarter ended March 31, 2019.

Cash Guidance

Alpine expects to have sufficient cash to fund its planned operations for at least the next 12 months, including the clinical advancement of Alpine's lead autoimmune/inflammatory program, ALPN-101, and its lead oncology program, ALPN-202.

For additional information regarding Alpine's planned operations, please refer to “Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operation - Liquidity and Capital Resources” in Alpine's Quarterly Report on

Form 10-Q for the three months ended March 31, 2020, which Alpine anticipates filing with the Securities and Exchange Commission on or about May 14, 2020.

About ALPN-101

ALPN-101 is a novel Fc fusion protein of a human inducible T cell costimulator ligand (ICOSL) variant immunoglobulin domain (vIgD™), a first-in-class therapeutic designed to inhibit simultaneously the CD28 and ICOS inflammation pathways. CD28 and ICOS are closely related costimulatory molecules with partially overlapping roles in T cell activation likely playing a role in multiple autoimmune and inflammatory diseases. In preclinical models of graft versus host disease, inflammatory arthritis, connective tissue disease, and multiple sclerosis, ALPN-101 demonstrates efficacy superior to agents blocking the CD28 - CD80/86 and/or ICOS - ICOSL pathways alone. A phase 1b/2 trial of ALPN-101 in acute GVHD (BALANCE, NCT04227938) has been initiated.

About ALPN-202

ALPN-202 is a first-in-class, conditional CD28 costimulator and dual checkpoint inhibitor with the potential to improve upon the efficacy of combined checkpoint inhibition while limiting significant toxicities. Preclinical studies of ALPN-202 have successfully demonstrated superior efficacy in tumor models compared to checkpoint inhibition alone. A phase 1 trial of ALPN-202 in advanced malignancies (NEON-1, NCT04186637) is open for enrollment.

About Alpine Immune Sciences, Inc.

Alpine Immune Sciences, Inc. is committed to leading a new wave of immune therapeutics, creating potentially powerful multifunctional immunotherapies to improve patients' lives via unique protein engineering technologies. Alpine has two programs in clinical development. The first, ALPN-101 for autoimmune/inflammatory diseases, is a selective dual T cell costimulation antagonist engineered to reduce pathogenic T and B cell immune responses by inhibiting ICOS and CD28. ALPN-101 has recently completed enrollment of a phase 1 healthy volunteer study, and BALANCE, a phase 1b/2 study in acute GVHD, has recently been initiated. The second, ALPN-202 for cancer, is a conditional CD28 costimulator and dual checkpoint inhibitor, and enrollment is open in NEON-1, a phase 1 study in advanced malignancies. Alpine is backed by world-class research and development capabilities, a highly productive scientific platform, and a proven management team. For more information, visit www.alpineimmunesciences.com.

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 pre-clinical development activities, clinical and regulatory objectives and the timing thereof, expectations regarding the sufficiency of cash to fund operations, the potential efficacy, safety profile, future development plans, addressable market, regulatory success, and commercial potential of our product candidates, the timing of our public presentations and potential publication of future clinical data, the efficacy of our clinical trial designs, 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; our ongoing discovery and pre-clinical efforts may not yield additional product candidates; our discovery-stage and pre-clinical 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; 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.

“Secreted Immunomodulatory Proteins”, “SIP”, “Transmembrane Immunomodulatory Protein,” “TIP,” “Variant Ig Domain,” “vIgD” and the Alpine logo are registered trademarks or trademarks of Alpine Immune Sciences, Inc. in various jurisdictions.

Alpine Immune Sciences, Inc.

Selected Consolidated Balance Sheet Data

(In thousands)

	March 31, 2020	December 31, 2019
	(unaudited)	
Cash and cash equivalents	\$ 24,446	\$ 16,123
Short-term investments	11,237	24,397
Total current assets	38,088	42,302
Total assets	49,849	54,093
Total current liabilities	5,105	8,681
Total stockholders' equity	24,859	29,474
Total liabilities and stockholders' equity	49,849	54,093

Consolidated Statement of Operations and
Comprehensive Income (Loss) Data*(In thousands, except share and per share amounts)*

	Three Months Ended March 31,	
	2020	2019
	(unaudited)	
Collaboration revenue	\$ 1,091	\$ —
Operating expenses:		
Research and development	4,878	10,350
General and administrative	1,778	2,345
Total operating expenses	6,656	12,695
Loss from operations	(5,565)	(12,695)
Other income (expense):		
Interest expense	(120)	(70)
Interest income	152	384
Net loss	\$ (5,533)	\$ (12,381)
Comprehensive income (loss):		
Unrealized (loss) gain on investments	(15)	15
Unrealized loss on foreign currency translation	(113)	(14)
Comprehensive loss	\$ (5,661)	\$ (12,380)
Weighted-average shares used to compute basic and diluted net loss per share	18,587,892	17,671,918
Basic and diluted net loss per share	\$ (0.30)	\$ (0.70)

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