

**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 30, 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(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ALPN	The Nasdaq Global 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 March 30, 2020, Alpine Immune Sciences, Inc. issued a press release reporting its financial results for the fourth quarter and fiscal year ended December 31, 2019. 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 March 30, 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 Provides Corporate Update and Reports Fourth Quarter and Full Year 2019 Financial Results

- **Completion of Phase 1 Study for Lead Autoimmune/Inflammatory Disease Program, ALPN-101**
- **BALANCE Trial of ALPN-101 in Acute GVHD Open for Enrollment**
- **NEON-1 Trial of ALPN-202 in Advanced Malignancies Open for Enrollment**
- **Orphan Drug Designations by the U.S. FDA for ALPN-101 for the Treatment and Prevention of Acute GVHD**
- **Conference Call Scheduled for 4:30 p.m. ET Today**

SEATTLE, WA - March 30, 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 fourth quarter and year ended December 31, 2019.

“This past year has been a very productive year for the company. We received orphan drug designations from the FDA, presented updated data at multiple conferences including ASH, ACR, SITC, and the Crohn’s & Colitis Congress, and completed enrollment in our Phase 1 study of ALPN-101, our lead therapeutic for the potential treatment of autoimmune and inflammatory diseases,” said Mitchell H. Gold, M.D., Executive Chairman and Chief Executive Officer of Alpine. “We have opened enrollment in BALANCE, a trial for ALPN-101 in acute GVHD, and NEON-1, a trial for ALPN-202 in advanced malignancies, beginning the next phase of evolution for the company as we test these novel molecules in patients in need of better therapeutic options.”

Recent Corporate and Clinical Highlights

Key Clinical and Preclinical Data Presentations at Biomedical Meetings: We showcased clinical and/or preclinical data for our lead programs, ALPN-101 and ALPN-202, at the following recent medical meetings:

- **Initial ALPN-101 phase 1 healthy volunteer study data presented at the American Society of Hematology meeting in December:** In adult healthy volunteers, ALPN-101 was well tolerated as single intravenous or subcutaneous doses, without cytokine release, infusion-related reactions, hypersensitivity, or other signs of agonist activity. Dose-dependent pharmacodynamic activity was observed, including inhibition of T cell activation, assessed *ex vivo* based on inhibition of staphylococcal enterotoxin B (SEB)-induced cytokine production, and inhibition of antibody responses, assessed following immunization with keyhole limpet hemocyanin (KLH). Based on activity in models, together with favorable tolerability and pharmacodynamics in healthy volunteers, ALPN-101 has the potential to be a clinically meaningful immunomodulator for the treatment of inflammatory diseases such as GVHD.
- **ALPN-101 preclinical data presented at ACR:** The two posters presented a unique potency of ALPN-101, often superior even to combinations of biologics individually targeting the CD28 and ICOS pathways, as measured by *in vitro* assays involving patient-derived immune cells and *in vivo* mouse models of inflammatory arthritis, lupus, and Sjögren’s Syndrome.
- **ALPN-202 preclinical data presented in posters at SITC:** One poster presented mechanistic data supporting ALPN-202 inhibits both the PD-L1 and CTLA-4 checkpoint pathways while also providing PD-L1-dependent CD28 costimulation, as intentionally designed. A second poster demonstrated the ability of ALPN-202 to improve significantly upon the activity of existing cancer therapeutics when given alone and/or in combination in preclinical models. In addition, crystallographic study suggested ALPN-202 binds PD-L1 and CD28 at distinct, non-overlapping epitopes enabling its potentially unique functionality.
- **ALPN-101 preclinical data in IBD presented at 2020 Crohn’s & Colitis Congress:** These new data showed 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 the CD4+CD45RBhi T cell transfer mouse colitis model.

ALPN-101 Received FDA Orphan Drug Designations for the Prevention and Treatment of Acute Graft Versus Host Disease: Earlier this month, the United States Food and Drug Administration (FDA) granted two orphan drug designations for ALPN-101, one for the prevention of and one for the treatment of acute GVHD.

Clinical Trials in Patients Now Open for Both Development Programs: A phase 1b/2 trial of ALPN-101 in acute GVHD (BALANCE, NCT04227938) and a phase 1 trial of ALPN-202 in advanced malignancies (NEON-1, NCT04186637) are now both open for enrollment.

Full Year 2019 Financial Results

As of December 31, 2019, we had cash, cash equivalents, restricted cash, and short-term investments totaling \$40.9 million. Net cash used in operating activities for the year ended December 31, 2019 was \$35.3 million compared to \$28.4 million for the year ended December 31, 2018. We recorded a net loss of \$41.9 million and \$36.5 million for the years ended December 31, 2019 and 2018, respectively.

Collaboration revenue for the year ended December 31, 2019 was \$1.7 million compared to \$0.7 million for the year ended December 31, 2018. The increase was primarily attributable to \$1.3 million in revenue recognized from the Adaptimmune Collaboration Agreement and a \$0.4 million milestone payment from Laurel from the sale of our GSNOR assets.

Research and development expenses for the year ended December 31, 2019 were \$35.8 million compared to \$29.0 million for the year ended December 31, 2018. The increase was primarily attributable to an increase in clinical trial activity, direct research activities, personnel-related expenses as a result of growth in headcount to support ongoing discovery and development programs, related overhead and facility costs for these programs, and an increase in stock-based compensation.

General and administrative expenses for the year ended December 31, 2019 were \$9.5 million compared to \$8.4 million for the year ended December 31, 2018. The increase was primarily attributable to personnel-related expenses related to an increase in administrative headcount, increases in professional and legal services, and an increase in facility costs to support the growth of our business.

Fourth Quarter and Full Year 2019 Conference Call and Webcast Details

Alpine will hold a conference call and webcast to discuss results from the fourth quarter and full year 2019 on March 30, 2020 at 4:30 pm EDT. To access the live call by phone, dial (800) 816-3005 (domestic) or (857) 770-0069 (international) using participant passcode 6877935. To access a live webcast of the call, please visit the Investor Relations section of the Alpine Immune Sciences website at ir.alpineimmunesciences.com. The recorded webcast will be available for replay for approximately 30 days following the call.

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) is open for enrollment.

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 a phase 1 healthy volunteer study, and enrollment is currently open in BALANCE, a phase 1b/2 study in acute GVHD. 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)

	December 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 16,123	\$ 10,711
Short-term investments	24,397	41,592
Total current assets	42,302	53,545
Total assets	54,093	54,873
Total current liabilities	8,681	8,127
Total stockholders' equity	29,474	44,591
Total liabilities and stockholders' equity	54,093	54,873

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,	
	2019	2018	2019	2018
	(unaudited)			
Collaboration revenue	\$ 884	\$ —	\$ 1,740	\$ 705
Operating expenses:				
Research and development	5,799	8,931	35,847	28,970
General and administrative	2,102	2,514	9,467	8,362
Loss on sale of intangible asset	—	—	—	1,203
Total operating expenses	7,901	11,445	45,314	38,535
Loss from operations	(7,017)	(11,445)	(43,574)	(37,830)
Other income (expense):				
Bargain purchase gain	—	—	—	—
Interest and other expense	(141)	(76)	(338)	(319)
Interest income	206	325	1,248	1,296
Other income	812	—	812	—
Loss before taxes	(6,140)	(11,196)	(41,852)	(36,853)
Income tax benefit	—	61	—	366
Net loss	\$ (6,140)	\$ (11,135)	\$ (41,852)	\$ (36,487)
Comprehensive income (loss):				
Unrealized gain (loss) on investments	(8)	12	29	46
Unrealized loss on foreign currency translation	11	—	(6)	—
Comprehensive loss	\$ (6,137)	\$ (11,123)	\$ (41,829)	\$ (36,441)
Weighted-average shares used to compute basic and diluted net loss per share	18,587,817	13,852,729	18,358,864	13,849,470
Basic and diluted net loss per share	\$ (0.33)	\$ (0.80)	\$ (2.28)	\$ (2.63)

Alpine Immune Sciences Inc.

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