

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**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 13, 2019**

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**ALPINE IMMUNE SCIENCES, INC.**

(Exact name of registrant as specified in its Charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-37449**  
(Commission  
File Number)

**20-8969493**  
(IRS Employer  
Identification No.)

**201 Elliott Avenue West, Suite 230  
Seattle, WA 98119**  
(Address of principal executive offices)

**Registrant's telephone number including area code: (206) 788-4545**  
(Former name or former address, if changed since last report)

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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.

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**Item 2.02 Results of Operations and Financial Condition.**

On November 13, 2019, Alpine Immune Sciences, Inc. issued a press release reporting its financial results for the third quarter of 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	<a href="#">Press Release dated November 13, 2019.</a>

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.

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**Alpine Immune Sciences Provides Corporate Update and  
Reports Third Quarter 2019 Financial Results**

*Company Advancing ALPN-101 into a Phase 1/2 Acute Graft versus Host Disease Study (BALANCE)*

*Phase 1 Study (NEON-1) of Lead Oncology Program ALPN-202 Planned to Commence in Q1 2020*

*Conference Call Scheduled for 4:30 p.m. ET Today*

SEATTLE, WA - November 13, 2019 - Alpine Immune Sciences, Inc. (NASDAQ:ALPN), a leading clinical-stage immunotherapy company focused on developing innovative treatments for cancer, autoimmune/inflammatory, and other diseases, today reported a corporate update and financial results for the third quarter ended September 30, 2019.

“The third quarter of 2019 included several significant milestones for Alpine, highlighted by completion of enrollment in our Phase 1 study in healthy volunteers for our lead program, ALPN-101,” said Mitchell H. Gold, MD, Executive Chairman and Chief Executive Officer of Alpine. “We believe ALPN-101 has the potential to deliver significantly differentiated efficacy outcomes across a range of inflammatory and autoimmune diseases. We look forward to highlighting our upcoming Phase 1/2 BALANCE study of ALPN-101 during an oral presentation at the ASH annual meeting next month.”

“In addition, we are actively preparing for the initiation of the Phase 1 NEON-1 study of our lead immuno-oncology program, ALPN-202,” Dr. Gold said. “At Alpine, we share a deep commitment and drive to deliver the next generation of immunotherapies to patients suffering from debilitating and deadly diseases and I am proud of the work our entire team has done in the transformation of Alpine to an established, clinical-stage company.”

**Recent Pipeline and Company Highlights**

*ALPN-101 Clinical Advancement*

- **Completed enrollment of Phase 1 Study of ALPN-101:** On October 30, 2019, Alpine announced completion of enrollment of its Phase 1 study of ALPN-101, a first-in-class dual ICOS/CD28 antagonist. Results from this trial will help inform further development of ALPN-101 in serious autoimmune and inflammatory diseases.
    - Overall, ALPN-101 was generally well-tolerated, without evidence of cytokine storm, cytokine release, or clinical immunogenicity while being dosed as single or multiple doses, intravenously or subcutaneously.
    - Preliminary analyses indicate well-behaved pharmacokinetics and pharmacodynamics, including on-target inhibition of immune functionality, such as antibody responses to keyhole limpet hemocyanin (KLH) and ex vivo staphylococcal enterotoxin B (SEB)-induced cytokine responses.
    - These initial findings will be included as part of an oral presentation at ASH next month, and further details after completion of final analyses are expected to be reported in presentations in the first half of 2020.
  - **New ALPN-101 Data Presented at American College of Rheumatology (ACR) Annual Meeting:** Earlier this week, Alpine presented new preclinical data on ALPN-101 in two posters during sessions at ACR. The new data highlighted ALPN-101’s novel dual mechanism of action which modulates unique inflammatory pathways, distinct from the other biologic therapies singly targeting the ICOS or CD28 pathways, and results in potent efficacy in multiple disease models. The full posters from ACR can be viewed at <https://www.alpineimmunesciences.com/pipeline/autoimmune-inflammation/>.
  - **Upcoming Oral Presentation at American Society of Hematology (ASH) Annual Meeting** Alpine will present on its upcoming Phase 1/2 BALANCE study of ALPN-101 in steroid-resistant or steroid-refractory acute Graft-versus-Host Disease (GvHD). Dr. Jan Hillson, Senior Vice President, Clinical Development for Alpine, will present on
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December 8, 2019 at 11:00 a.m. ET. The full abstract can be viewed at <https://ash.confex.com/ash/2019/webprogram/Paper126034.html>.

### ***ALPN-202 Preparing for Phase I Study***

- **New ALPN-202 Data Presented at Society for Immunotherapy of Cancer (SITC) Annual Meeting:** On November 8, 2018, Alpine presented two posters with new preclinical data on its lead oncology program ALPN-202, a conditional CD28 costimulator and dual checkpoint inhibitor. The new preclinical data further highlight ALPN-202's novel mechanism of action and its superior anti-tumor activity, as well as its potential to be uniquely effective as a monotherapy and in combination with immune checkpoint inhibitors or chemotherapy. The full posters from SITC can be viewed at <https://www.alpineimmunesciences.com/pipeline/oncology/>.
- Data presented at SITC supports the advancement of ALPN-202 towards its first Phase 1 clinical trial, which Alpine expects to initiate, upon authorization, in the first quarter of 2020.

### **Financial Results for Third Quarter and Nine Months Ended September 30, 2019**

Alpine recorded a net loss of \$11.5 million and \$12.1 million for the third quarters ended September 30, 2019 and 2018, respectively, and \$35.7 million and \$25.4 million for the nine months ended September 30, 2019 and 2018, respectively.

Research and development expenses for the third quarter ended September 30, 2019 were \$9.5 million compared to \$10.5 million for the third quarter ended September 30, 2018. For the nine months ended September 30, 2019 and 2018, research and development expenses were \$30.0 million and \$20.0 million, respectively. The company expects a continued increase to research and development activities to support the clinical advancement of its ALPN-101 and ALPN-202 programs.

General and administrative expenses for the third quarter ended September 30, 2019 were \$2.5 million compared to \$1.9 million for the third quarter ended September 30, 2018. For the nine months ended September 30, 2019 and 2018, general and administration expenses were \$7.4 million and \$5.8 million, respectively. The increase was primarily attributable to professional and legal services and an increase in facility costs to support the growth and expansion of our business.

### **Cash Position**

As of September 30, 2019, Alpine had cash, cash equivalents, restricted cash, and short-term investments totaling \$47.0 million. For the nine months ended September 30, 2019, net cash used in operating activities was \$29.7 million compared to \$19.0 million for the nine months ended September 30, 2018.

Management will provide updates to cash guidance on the conference call scheduled to discuss third quarter 2019 financial results.

### **Conference Call and Webcast Details**

Alpine will host a conference call to discuss key data, clinical highlights and provide an update on third quarter 2019 results on Wednesday, November 13, 2019 at 4:30 p.m. ET. To access the live call by phone, dial (877) 407-0789 (domestic) or (201) 689-8562 (international). To access a live webcast of the call, please visit the Investor Relations section of the Alpine Immune Sciences website at [www.alpineimmunesciences.com](http://www.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™), and 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 connected to 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 blockade of the CD28 or ICOS pathways alone.

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## **About ALPN-202**

ALPN-202 is a first-in-class, conditional CD28 costimulator and dual checkpoint inhibitor, which has the potential to improve upon the efficacy of combined checkpoint inhibition without significant toxicities. Preclinical studies of ALPN-202 have successfully demonstrated superior efficacy in tumor models compared to checkpoint inhibition alone. We anticipate initiation, upon authorization, of the first-in-human clinical study of ALPN-202 to begin in the first quarter of 2020.

## **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 lead programs. The first, ALPN-101 for autoimmune/inflammatory diseases, is a selective dual T-cell costimulation blocker engineered to reduce pathogenic T and B cell immune responses by blocking ICOS and CD28. ALPN-101 has recently completed enrollment in a phase I healthy volunteer trial. The second, ALPN-202 for cancer, is a conditional CD28 costimulator and dual checkpoint inhibitor. 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](http://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.*

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**Alpine Immune Sciences, Inc.**

## Selected Condensed Consolidated Balance Sheet Data

*(In thousands)*

	September 30, 2019	December 31, 2018
	(unaudited)	
Cash and cash equivalents	\$ 17,395	\$ 10,711
Short-term investments	29,193	41,592
Total current assets	52,454	53,545
Total assets	64,739	54,873
Total current liabilities	13,672	8,127
Total stockholders' equity	34,831	44,591
Total liabilities and stockholders' equity	64,739	54,873

## Condensed 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,	
	2019	2018	2019	2018
	(unaudited)			
Collaboration revenue	\$ 289	\$ —	\$ 856	\$ 705
Operating expenses:				
Research and development	9,532	10,529	30,048	20,039
General and administrative	2,467	1,857	7,365	5,848
Loss on sale of intangible asset	—	—	—	1,203
Total operating expenses	11,999	12,386	37,413	27,090
Loss from operations	(11,710)	(12,386)	(36,557)	(26,385)
Other income (expense):				
Interest expense	(66)	(82)	(197)	(243)
Interest and other income	301	329	1,042	971
Loss before taxes	(11,475)	(12,139)	(35,712)	(25,657)
Income tax benefit	—	—	—	305
Net loss	\$ (11,475)	\$ (12,139)	\$ (35,712)	\$ (25,352)
Comprehensive income (loss):				
Unrealized gain on investments	5	30	37	34
Unrealized loss on foreign currency translation	(7)	—	(17)	—
Comprehensive loss	\$ (11,477)	\$ (12,109)	\$ (35,692)	\$ (25,318)
Weighted-average shares used to compute basic and diluted net loss per share	18,586,950	13,851,336	18,281,707	13,848,371
Basic and diluted net loss per share	\$ (0.62)	\$ (0.88)	\$ (1.95)	\$ (1.83)

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