

**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): June 17, 2020

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, 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 x

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. x

Item 1.01 Entry into a Material Definitive Agreement.

On June 17, 2020, Alpine Immune Sciences, Inc. (the “Company”) entered into an Option and License Agreement (the “Agreement”) with AbbVie Ireland Unlimited Company (“AbbVie”), which Agreement grants to AbbVie an exclusive option to take an exclusive license to the Company’s clinical candidate ALPN-101, a dual inducible T-cell costimulatory (“ICOS”) and cluster of differentiation 28 (“CD28”) antagonist intended for the treatment of autoimmune and inflammatory diseases.

Exclusive Option and License. Under the terms of the Agreement the Company granted to AbbVie an exclusive option to obtain an exclusive, royalty-bearing, sublicensable license to certain of the Company’s intellectual property rights for the research, development and commercialization of ALPN-101 and any other molecule owned or controlled by the Company that binds to or directly modulates or targets ICOS at certain agreed-upon levels (collectively, the “Compounds”), on a worldwide basis for all human and non-human diagnostic, prophylactic and therapeutic uses, subject to certain exceptions set forth in the Agreement (the “Option”). The Option is immediately exercisable and will expire 90 days following the delivery by the Company of the Option Exercise Data Package (as defined below) to AbbVie, subject to certain exceptions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the “HSR Act”), if required.

Financial Terms. In connection with the execution of the Agreement, AbbVie agreed to pay the Company an upfront payment of \$60.0 million in cash. If AbbVie exercises the Option, AbbVie will pay the Company a one-time cash payment of \$75.0 million.

In addition to the upfront payment and Option exercise payment, AbbVie has agreed to make cash payments to the Company upon the Company’s achievement of certain development milestones prior to the exercise of the Option as set forth in a written development plan (the “Development Plan”), up to an aggregate amount of \$75.0 million. AbbVie has also agreed to make cash payments to the Company in the period following the exercise of the Option upon AbbVie’s achievement of certain development and commercial milestones, up to an aggregate amount of \$205.0 million. AbbVie will also make certain sales-based cash milestone payments to the Company upon the achievement of certain annual net sales targets up to an aggregate of \$450.0 million.

AbbVie has further agreed to pay the Company royalties based on future net sales of any pharmaceutical product that contains a Compound (each, a “Licensed Product”). Such royalty percentages range from a high-single digit percentage to a low double-digit percentage of net sales, with the specific royalty rate depending on the aggregate net sales. AbbVie’s obligations to pay royalties with respect to a Licensed Product and country will expire upon the latest of the expiration of the last to expire valid patent claim applicable to such Licensed Product in such country, 10 years from the first commercial sale of the Licensed Product in such country, and the expiration of regulatory exclusivity for such Licensed Product in such country (the “Royalty Term”). Royalty payments are subject to reduction in specified circumstances, including expiration of patent rights, if average net sales decrease by a certain percentage after the introduction of a generic product, or if AbbVie is required to pay amounts to a third party in order commercialize a Licensed Product in a particular country.

Development Activities; Regulatory Matters; Manufacturing. Prior to the exercise of the Option, the Company will conduct its development efforts under the Development Plan providing for, among other things, the generation of a data package in order for AbbVie to evaluate exercising the Option (the “Option Exercise Data Package”) and an itemized budget for such activities, including all activities reasonably necessary to complete a Phase II clinical study of a Compound for the treatment of systemic lupus erythematosus (a “Phase II SLE Clinical Study”); all non-clinical toxicology activities; and all CMC activities required under the Development Plan (collectively, such activities under the Development Plan are referred to as the “Development Activities”). The Company will be fully responsible for all costs incurred to conduct its activities under the Development Plan, provided that, AbbVie may be responsible for increased costs under the Development Plan in connection with certain material amendments proposed by AbbVie.

Prior to the exercise of the Option, the Company will be solely responsible, at its sole cost and expense, for preparing, filing and maintaining regulatory documentation, which AbbVie will be entitled to access and review. The Company shall also be responsible for any and all correspondence with the applicable regulatory authorities and for maintaining all data related to any of the Compounds. The Company will be solely responsible, at its sole cost and expense, for manufacturing the Compounds necessary to complete the Development Activities consistent with the Development Plan.

Governance. The parties will establish a joint governance committee (“JGC”) composed of an equal number of representatives from each of the Company and AbbVie, which will, among other responsibilities, coordinate and oversee the Development Activities, approve amendments to the Development Plan and discuss interactions with regulatory authorities. The chairperson of the JGC will be appointed by AbbVie. AbbVie may disband the JGC, at its sole discretion, following the exercise of the Option.

Commercialization. Upon AbbVie's exercise of the Option, AbbVie and its affiliates will be solely responsible, at AbbVie's sole cost and expense, for the development, manufacture, commercialization and regulatory compliance of any Licensed Product. Following exercise of the Option, AbbVie shall use commercially reasonable efforts to develop and seek regulatory approval for one of the Compounds in one indication in each of the United States and one of the United Kingdom, Germany, France, Spain or Italy (collectively, and together with the United States, the "Major Markets") and, following receipt of any such regulatory approval, commercialize the compound in such country.

Changes in Control. The Company will notify AbbVie immediately upon the closing of any change in control (as defined in the Agreement) during the term of the Agreement. Following the delivery of such notice, AbbVie may, in its sole and absolute discretion, elect to continue the Agreement subject to certain modifications as set forth in the Agreement, including the assumption by AbbVie of responsibility to perform certain activities previously assigned to the Company.

Term and Termination. Unless earlier terminated, the Agreement shall terminate either: (i) in the event that the Option is not exercised by AbbVie, the first day following the last day of the Option exercise period; or (ii) in the event that the Option is exercised by AbbVie, the date of the expiration of the last Royalty Term for the last Licensed Product.

Both the Company and AbbVie may terminate the Agreement upon written notice in the event of a material breach by the other party that has not been cured within a 90-day cure period. However, if the uncured material breach is with respect to AbbVie's obligation to use commercially reasonable efforts to obtain regulatory approval for and commercialize a Licensed Product with respect to any Major Market (but not all Major Markets), then the Company will only be entitled to terminate the Agreement with respect to such Major Market(s). Both the Company and AbbVie may also terminate the Agreement upon written notice if the other party voluntarily or involuntarily files for bankruptcy or insolvency, makes an assignment for the benefit of creditors, has a receiver or trustee appointed over substantially all of such other party's property, proposes or is party to any dissolution or liquidation, or admits in writing its inability generally to meet such other party's obligations as they fall due in the general course.

AbbVie may terminate the Agreement in its entirety or on a country-by-country basis, for any or no reason, by providing at least 90 days' prior written notice to the Company. AbbVie may also terminate the Agreement upon notice to the Company if (i) either the Company or AbbVie receives a second request for additional information under the HSR Act, provided AbbVie's notice of termination is delivered within ten business days after AbbVie becomes aware of such request or receives notice from the Company regarding such request or (ii) the Option has not been exercised or clearance under the HSR Act, if required, has not occurred within 180 days of submission of the parties' request for such clearance, provided AbbVie's notice of termination is delivered within ten business days after the end of such 180-day period.

Upon the termination of the Agreement in its entirety for any reason, all licenses and other rights granted (i) to AbbVie by the Company and (ii) to the Company by AbbVie shall terminate. Upon termination in certain circumstances, AbbVie has agreed to grant to the Company licenses to certain intellectual property that is reasonably necessary, and that was actually used by AbbVie for the development, manufacturing or commercialization of the terminated products, to research, develop and commercialize the terminated products in the terminated countries.

In lieu of terminating the Agreement in connection with an uncured material breach or the bankruptcy or insolvency of the Company, AbbVie may alternatively elect to continue the Agreement subject to certain modifications, including that AbbVie will be entitled to conduct activities allocated to the Company under the Development Plan, subject to reimbursement by the Company for AbbVie's out-of-pocket expenses in connection with such activities. If AbbVie's right to terminate in connection with an uncured material breach or the bankruptcy or insolvency of the Company arises before exercise of the Option, then the Option exercise payment amount will be reduced by half and the amount of any then-earned milestone payments will be reduced by half. If AbbVie's right to terminate arises after exercise of the Option, then the amount of any then-earned milestone payments will be reduced by 25%.

The Agreement includes certain other customary terms and conditions, including mutual representations and warranties, indemnification and confidentiality provisions.

The foregoing description of the Agreement is not complete and is qualified in its entirety by reference to the full text of the Agreement. A copy of the Agreement will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. On June 18, 2020, the Company and AbbVie Inc. issued a joint press release announcing the entry into the Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

As a result of the receipt of the upfront payment of \$60.0 million pursuant to the Agreement and based on current assumptions, the Company anticipates having sufficient cash to fund its planned operations into 2023, excluding any revenue generated from existing partnerships or potential new partnering arrangements.

The information set forth in this Item 7.01 is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

For strategic reasons, the Company will cease enrollment in and intends to terminate BALANCE, the Company’s Phase 1b/2, open-label, dose escalation and expansion trial of ALPN-101 in patients with steroid-resistant or steroid-refractory active acute graft-versus-host disease.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Joint Press Release issued by Alpine Immune Sciences, Inc. and AbbVie Inc., dated June 18, 2020.

Alpine Immune Sciences and AbbVie Announce Option and License Agreement for the Development and Commercialization of ALPN-101

- *Alpine Immune Sciences grants AbbVie option to license worldwide rights to ALPN-101, a phase 2-ready, first-in-class dual CD28/ICOS costimulation antagonist, building on AbbVie's commitment to developing novel therapies in Immunology*
- *Alpine Immune Sciences to receive \$60 million in an upfront cash payment; eligible to receive up to \$805 million for exercise of the option and success-based development, regulatory and commercial milestones*
- *Alpine Immune Sciences to conduct a phase 2 study in systemic lupus erythematosus during the option period*
- *Alpine will host a conference call today at 8:30 a.m. ET -*

SEATTLE, WA and NORTH CHICAGO, Ill., June 18, 2020 -- Alpine Immune Sciences, Inc. (NASDAQ: ALPN), a leading clinical-stage immunotherapy company focused on developing innovative treatments for cancer and autoimmune/inflammatory diseases, and AbbVie Inc. (NYSE: ABBV), a research-based global biopharmaceutical company, today announced an exclusive worldwide option and license agreement for ALPN-101, a first-in-class dual CD28/ICOS costimulation antagonist.

CD28 and ICOS are key costimulatory molecules that likely play critical roles in multiple autoimmune and inflammatory diseases. ALPN-101 is a potent inhibitor of both CD28 and ICOS pathways with demonstrated efficacy in multiple preclinical disease models, superior to blockade of either pathway alone. Favorable safety and tolerability, pharmacokinetics and pharmacodynamics have been observed in a first-in-human study in adult healthy volunteers.

"We are very pleased to partner ALPN-101 with AbbVie, a world leader in the development and commercialization of innovative immunology therapies," said Mitchell H. Gold, M.D., Executive Chairman and Chief Executive Officer of Alpine Immune Sciences. "AbbVie is an ideal partner for ALPN-101, with the therapeutic area expertise, R&D commitment, and global resources needed to maximize ALPN-101's potential for patients suffering from autoimmune diseases. Today's agreement validates our unique Directed Evolution platform that has yielded multiple product candidates, including ALPN-101. We look forward to working with our colleagues at AbbVie to potentially transform clinical outcomes in systemic lupus erythematosus, a disease with currently few appealing treatment options."

"AbbVie's expertise in Immunology has led to remarkable breakthroughs in the treatment of autoimmune diseases," said Tom Hudson, M.D., Senior Vice President and Chief Scientific Officer, AbbVie. "ALPN-101's dual mechanism of action has compelling potential as a next-generation treatment in systemic lupus erythematosus and other autoimmune diseases. We are excited to partner with the team at Alpine on the development of this novel therapeutic."

Under the terms of the agreement, Alpine will receive an upfront payment of \$60 million, and will also be eligible to receive up to an aggregate of \$805 million for exercise of the option and success-based development, regulatory and commercial milestones. In addition, Alpine is eligible to receive tiered royalties on net sales of ALPN-101. In exchange, AbbVie will receive an option to an exclusive license for ALPN-101. During the option period, Alpine will conduct a phase 2 study in systemic lupus erythematosus. Upon exercise of the option, AbbVie will conduct all future clinical development, manufacturing and commercialization activities for ALPN-101.

Alpine Immune Sciences will host a conference call today at 8:30 a.m. ET to discuss the option and license agreement and outline the company's strategic focus moving forward.

Conference Call and Webcast Details

Alpine Immune Sciences will host a conference call today at 8:30 a.m. ET to discuss today's announcement. To access the live call by phone, dial (800) 816-3005 (domestic) or (857) 770-0069 (international) using participant passcode 3770288. To access a live webcast of the call, please visit the Investor Relations section of the Alpine Immune Sciences website at www.alpineimmunesciences.com. The recorded webcast will be available for replay for approximately 30 days following the call.

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 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. Follow [@AlpineImmuneSci](https://twitter.com/AlpineImmuneSci) on [Twitter](https://twitter.com/AlpineImmuneSci) and [LinkedIn](https://www.linkedin.com/company/alpine-immune-sciences).

About AbbVie

AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com. Follow [@abbvie](https://twitter.com/abbvie) on [Twitter](https://twitter.com/abbvie), [Facebook](https://www.facebook.com/abbvie), [Instagram](https://www.instagram.com/abbvie), [YouTube](https://www.youtube.com/abbvie) and [LinkedIn](https://www.linkedin.com/company/abbvie).

Forward-Looking Statements

Alpine Immune Sciences, Inc:

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, including those related to our collaboration with AbbVie; clinical and regulatory objectives and the timing thereof; the potential efficacy, safety profile, future development plans, addressable market, regulatory success, and commercial potential of our product candidates, including those related to our collaboration with AbbVie; our ability to achieve milestones in our collaboration with AbbVie; the progress and potential of our other ongoing development programs; the efficacy of our clinical trial designs; expectations regarding our other 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 or our collaborators' 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 or our collaborators' 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 expanded product development and clinical activities on operating expenses; the impact of competition; adverse conditions in the general domestic and global economic markets, including as a result of the ongoing COVID-19 pandemic; 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.

AbbVie:

Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words “believe,” “expect,” “anticipate,” “project” and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, failure to realize the expected benefits from AbbVie’s acquisition of Allergan plc (“Allergan”), failure to promptly and effectively integrate Allergan’s businesses, competition from other products, challenges to intellectual property, difficulties inherent in the research and development process, adverse litigation or government action, changes to laws and regulations applicable to our industry and the impact of public health outbreaks, epidemics or pandemics, such as COVID-19. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, “Risk Factors,” of AbbVie's 2019 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission, as updated by its subsequent Quarterly Reports on Form 10-Q. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

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