
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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 12, 2022

ALTIMMUNE, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-32587
(Commission
File Number)

20-2726770
(IRS Employer
Identification No.)

910 Clopper Road, Suite 201S
Gaithersburg, Maryland
(Address of principal executive offices)

20878
(Zip Code)

Registrant's telephone number including area code: (240) 654-1450

(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 \$0.0001 per share | ALT | 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 May 12, 2022, Altimmune, Inc. (the “Company”) issued a press release announcing the Company’s financial results for its fiscal quarter ended March 31, 2022. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information included in this Current Report on Form 8-K (including Exhibit 99.1 hereto) that is furnished pursuant to this Item 2.02 shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. In addition, the information included in this Current Report on Form 8-K (including Exhibit 99.1 hereto) that is furnished pursuant to this Item 2.02 shall not be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference into such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

| <u>No.</u> | <u>Description</u> |
|------------|---|
| 99.1 | Press Release of Altimmune, Inc. dated May 12, 2022 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

SIGNATURE

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.

ALTIMMUNE, INC.

By: /s/ Richard Eisenstadt
Name: Richard Eisenstadt
Title: Chief Financial Officer

Dated: May 12, 2022

Altimune Announces First Quarter 2022 Financial Results and Provides a Corporate Update

Multiple clinical trial data readouts expected in Q3 and Q4 2022

GAITHERSBURG, MD, -- May 12, 2022 -- Altimune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three months ended March 31, 2022 and provided a corporate update.

“We continue to advance the development of pemvidutide, our GLP-1/Glucagon dual receptor agonist and look forward to reporting both weight loss and liver fat reduction data from multiple ongoing clinical trials later this year,” said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimune. “Based on a greater than 10% weight loss after only 12 weeks of treatment, we believe that pemvidutide has the potential to deliver weight loss comparable to the results of bariatric surgery in people with obesity. In addition, we believe that pemvidutide will have a highly differentiated product profile compared to other products in development—no dose titration, faster weight loss, and robust reductions in lipids. If achieved, we believe these features would translate into greater ease of administration, improved adherence to therapy, and greater potential for cardiovascular benefit.”

Recent Highlights and Anticipated Milestones:

Pemvidutide¹ (ALT-801)

- *Enrollment ongoing in 48-week Phase 2 MOMENTUM trial of pemvidutide in obesity*
 - This Phase 2 trial is being conducted at approximately 25 sites in the U.S., with Dr. Lou Aronne, Professor of Clinical Medicine, Weill Cornell Medical College, a leading authority in obesity and obesity clinical trials, serving as the Principal Investigator.
 - The trial is expected to enroll approximately 320 non-diabetic subjects with either obesity or overweight. Subjects are being randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 48 weeks.
 - The primary endpoint is the relative (percent) change in body weight at 48 weeks compared to baseline, with additional readouts including metabolic and lipid profiles, cardiovascular measures and glucose homeostasis.
 - Dosing has commenced and an interim analysis is planned to assess changes in body weight after 24 weeks of treatment, with an expected readout in Q4 2022.
- *Enrollment completed in 12-week Phase 1b nonalcoholic fatty liver disease (NAFLD) trial*
 - This Phase 1b trial is being conducted in the U.S., with Dr. Stephen A. Harrison, Director, Pinnacle Research and University of Oxford, serving as Principal Investigator.

¹ proposed INN



- The trial is comprised of non-diabetic and diabetic subjects randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 12 weeks.
- The primary efficacy readouts are liver fat reduction and weight loss at day 85 (12 weeks).
- Data readout expected in Q3 2022.
- *Enrollment ongoing in Phase 1b NAFLD extension trial*
 - This 12-week extension trial allows subjects who have completed the 12-week Phase 1b NAFLD trial to receive a total of 24 weeks of treatment, with an expected data readout on weight loss at 24 weeks in Q4 2022.
- *Enrollment ongoing in Phase 1b trial of diabetic subjects with obesity and overweight*
 - This 12-week trial will expand on findings from our first-in-human trial in subjects with obesity and overweight, in whom decreased insulin resistance and maintenance of glucose control were observed, including subjects with pre-diabetes.

Upcoming presentations summarizing data from the Phase 1 trial of pemvidutide at international Scientific Meetings

- May 27, 2022: Global NASH Congress, London UK –*The Emerging Weight Loss Therapeutics and Implications for the NASH Treatment Paradigm*. Oral presentation by Scott Harris, M.D., Chief Medical Officer, Altimune.
- June 6, 2022: American Diabetes Association (ADA) Scientific Sessions, New Orleans, LA – *Pemvidutide (ALT-801), a Balanced (1:1) GLP-1/Glucagon Dual Receptor Agonist, Induces Rapid and Marked Weight Loss without the Need for Dose Titration in People with Overweight/Obesity*. Oral presentation by Samuel Klein, M.D., William H. Danforth Professor of Medicine and Nutritional Science, Washington University School of Medicine.
- June 25, 2022: EASL International Liver Congress, London, UK –*Pemvidutide (ALT-801), a novel GLP-1/glucagon dual receptor agonist, induces significant reductions in major lipid classes implicated in the pathogenesis of NASH and other conditions*. Oral presentation by Stephen Harrison, M.D. Medical Director, Pinnacle Research and University of Oxford.

HepTcell

- *Enrollment continuing in the Phase 2 clinical trial in chronic hepatitis B, with data readout expected H1 2023*
 - Readouts are expected to include virological markers of hepatitis B infection and functional cure.

Financial Results for the Three Months Ended March 31, 2022

- Altimune had cash, cash equivalents and restricted cash totaling \$180.0 million at March 31, 2022.
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- Revenue was minimal for the three months ended March 31, 2022 compared to \$0.8 million in the same period in 2021. The change in revenue quarter over quarter was primarily due to the discontinuation of development activities for the T-COVID and NasoShield programs.
- Research and development expenses were \$15.1 million for the three months ended March 31, 2022, compared to \$11.9 million in the same period in 2021. The expenses for the quarter ended March 31, 2022 included \$10.8 million in direct costs related to development activities for pemvidutide and \$2.5 million in direct costs related to development activities for HepTcell.
- General and administrative expenses were \$4.4 million for the three months ended March 31, 2022, compared to \$3.8 million in the same period in 2021. The change was primarily attributable to increased stock compensation expense.
- Net loss for the three months ended March 31, 2022 was \$19.4 million, or \$0.44 net loss per share, compared to \$14.9 million in the same period in 2021, or \$0.38 net loss per share.
- 2022 operating expense guidance will be provided on the conference call.

Conference Call Information

Date: Thursday, May 12
Time: 8:30 am Eastern Time
Domestic Dial-in: (800) 225-9448
International Dial-in: (203) 518-9708
Conference ID: ALTQ122
Webcast: <https://edge.media-server.com/mmc/p/j5i9f735>

Following the conclusion of the call, the webcast will be available for replay on the Investor Relations page of the Company's website at www.altimmune.com. The Company has used, and intends to continue to use, the IR portion of its website as a means of disclosing material non-public information and for complying with disclosure obligations under Regulation FD.

About Pemvidutide

Pemvidutide is a novel, investigational, peptide-based GLP-1/glucagon dual receptor agonist in development for the treatment of obesity and NASH. Activation of the GLP-1 and glucagon receptors is believed to mimic the complementary effects of diet and exercise on weight loss, with GLP-1 suppressing appetite and glucagon increasing energy expenditure. By combining GLP-1 and glucagon activity in a single peptide, pemvidutide has the potential to achieve weight loss comparable to the results of bariatric surgery. Pemvidutide incorporates the EuPort™ domain, a proprietary technology that increases its serum half-life for weekly dosing while slowing the entry of pemvidutide into the bloodstream, which may improve its tolerability. In a 12-week Phase 1 clinical trial, pemvidutide-treated subjects demonstrated striking reductions in body weight, liver fat and serum lipids commonly associated with cardiovascular disease.



About HepTcell

HepTcell is a novel, investigational, immunotherapeutic comprised of nine synthetic peptides representing conserved hepatitis B (HBV) sequences formulated with IC31[®], a TLR9-based adjuvant from Valneva SE. The HBV-directed peptides are designed to drive T cell responses against all HBV genotypes towards a functional cure for chronic HBV in patients of diverse genetic backgrounds.

About Altimune

Altimune is a clinical-stage biopharmaceutical company focused on the development of novel peptide-based therapeutics for the treatment of obesity and liver diseases. The company's lead product candidate, pemvidutide, is a GLP-1/glucagon dual receptor agonist that is being developed for the treatment of obesity and NASH. In addition, Altimune is developing HepTcell[™], an immunotherapeutic designed to achieve a functional cure for chronic hepatitis B. For more information, please visit www.altimmune.com.

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Forward-Looking Statement

Any statements made in this press release relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, including without limitation, the timing of key milestones for our clinical assets, the timing of the data readouts of the NAFLD trials, drug-drug interaction trial, and the Phase 2 obesity clinical trial of pemvidutide, the timing of the data readouts for the Phase 2 clinical trial of HepTcell, and the prospects for regulatory approval, commercializing or selling any product or drug candidates, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Altimune, Inc. (the "Company") may identify forward-looking statements. The Company cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time. Important factors that may cause actual results to differ materially from the results discussed in the forward looking statements or historical experience include risks and uncertainties, including risks relating to: potential impacts from the ongoing conflict in Ukraine and the COVID-19 pandemic, such as delays in regulatory review, manufacturing and supply chain interruptions, access to clinical sites, enrollment, adverse effects on healthcare systems and disruption of the global economy; the reliability of the results of studies relating to human safety and possible adverse effects resulting from the administration of the Company's product candidates; the Company's ability to manufacture clinical trial materials on the timelines anticipated; and the success of future product advancements, including the success of future clinical trials. Further information on the factors and risks that could affect the Company's business, financial conditions and results of operations are contained in the Company's filings with the U.S. Securities and Exchange Commission, including under the heading "Risk Factors" in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2021 and our other filings with the SEC, which are available at www.sec.gov.



Investor & Media Contacts:

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ALTIMMUNE, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

| | March 31, 2022 (unaudited) | December 31, 2021 |
|--|----------------------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 179,947 | \$ 190,301 |
| Restricted cash | 34 | 34 |
| Total cash, cash equivalents and restricted cash | 179,981 | 190,335 |
| Accounts receivable | 193 | 429 |
| Income tax and R&D incentive receivables | 5,880 | 5,410 |
| Prepaid expenses and other current assets | 5,039 | 7,952 |
| Total current assets | 191,093 | 204,126 |
| Property and equipment, net | 1,337 | 1,448 |
| Intangible assets, net | 12,419 | 12,419 |
| Other assets | 811 | 872 |
| Total assets | \$ 205,660 | \$ 218,865 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,205 | \$ 2,034 |
| Contingent consideration | 4,310 | 6,090 |
| Accrued expenses and other current liabilities | 12,609 | 10,152 |
| Total current liabilities | 19,124 | 18,276 |
| Other long-term liabilities | 1,668 | 1,454 |
| Total liabilities | 20,792 | 19,730 |
| Commitments and contingencies (Note 16) | | |
| Stockholders' equity: | | |
| Common stock, \$0.0001 par value; 200,000,000 shares authorized; 43,219,896 and 40,993,768 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively | 4 | 4 |
| Additional paid-in capital | 502,505 | 497,342 |
| Accumulated deficit | (312,601) | (293,171) |
| Accumulated other comprehensive loss, net | (5,040) | (5,040) |
| Total stockholders' equity | 184,868 | 199,135 |
| Total liabilities and stockholders' equity | \$ 205,660 | \$ 218,865 |



ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share data)

| | For the Three Months Ended March 31, | |
|--|---|-------------|
| | 2022 | 2021 |
| Revenues | \$ 32 | \$ 838 |
| Operating expenses: | | |
| Research and development | 15,104 | 11,878 |
| General and administrative | 4,427 | 3,821 |
| Total operating expenses | 19,531 | 15,699 |
| Loss from operations | (19,499) | (14,861) |
| Other income (expense): | | |
| Interest expense | (62) | (12) |
| Interest income | 21 | 42 |
| Other income (expense), net | 110 | (33) |
| Total other income (expense), net | 69 | (3) |
| Net loss | (19,430) | (14,864) |
| Other comprehensive income — unrealized gain on short-term investments | — | 5 |
| Comprehensive loss | \$ (19,430) | \$ (14,859) |
| Net loss per share, basic and diluted | \$ (0.44) | \$ (0.38) |
| Weighted-average common shares outstanding, basic and diluted | 43,969,481 | 38,914,990 |