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): February 28, 2023

ALTIMMUNE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-32587**	**20-2726770**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 February 28, 2023, Altimmune, Inc. (the "Company") issued a press release announcing the Company's financial results for its full year and fiscal quarter ended December 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

No.	Description
99.1	Press Release of Altimmune, Inc. dated February 28, 2023
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: February 28, 2023

Exhibit 99.1

Altimmune Announces Fourth Quarter and Full Year 2022 Financial Results and Provides a Business Update

Interim 24-week readout from MOMENTUM Phase 2 obesity trial expected March 2023
Initiation of Phase 2b non-alcoholic steatohepatitis (NASH) trial expected mid-2023

Webcast to be held today, February 28, 2023, at 8:30 am ET

GAITHERSBURG, Maryland -- February 28, 2023 -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the fourth quarter and full year ended December 31, 2022, and provided a business update.

"The next twelve-months is an important period for potential value-creating data readouts and the clinical development of pemvidutide, our GLP-1/glucagon dual-receptor agonist which is being developed for the treatment of both obesity and NASH. We are looking forward to announcing the top-line 24-week interim results from our MOMENTUM Phase 2 obesity trial in the second half of March," said Vipin K. Garg, Ph.D., President and Chief Executive Officer of Altimmune. "In addition, based on the compelling data from our recently completed trial in non-alcoholic fatty liver disease (NAFLD), which included greater than a 75% reduction in liver fat content and significant reductions in non-invasive markers of liver inflammation, we expect to initiate a Phase 2b biopsy-driven trial of pemvidutide in NASH in mid-2023. We expect the key endpoints of this trial to be NASH resolution and fibrosis improvement, both assessed following 24 weeks of treatment. Pemvidutide possesses key attributes that we expect to be important for both obesity and NASH, including the potential for robust reductions in body weight, liver fat, and liver inflammation, along with positive effects on serum lipids and blood pressure. We believe that the absence of dose titration further distinguishes pemvidutide from other incretin-based agents."

Recent Highlights and Anticipated Milestones:

Pemvidutide

- *Positive top-line data readout from 24-week (12-week extension) Phase 1b NAFLD trial in December 2022*
    - Greater than a 75% relative reduction in liver fat content achieved, with over 50% of subjects achieving normalization of liver fat, at the 1.8 mg dose.
    - Significant reductions in serum alanine aminotransferase (ALT) and corrected T1 (cT1) observed, both established markers of liver inflammation, at the 1.8 mg dose.
    - Mean weight loss of 7.2% (placebo adjusted 6.0%) in subjects without diabetes, at the 1.8 mg dose.
    - Glycemic control maintained with trends toward improvements in fasting glucose and HbA1c in subjects with type 2 diabetes.
    - Low rates of treatment discontinuations due to adverse events.

- Clinically meaningful reductions in blood pressure with minimal increases in heart rate.

- *24-week interim analysis of approximately 160 subjects in MOMENTUM Phase 2 obesity trial expected in the second half of March 2023*
  - This Phase 2 trial is being conducted at 30 sites across 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 was designed to enroll approximately 320 non-diabetic subjects with obesity, or overweight with at least one co-morbidity. Subjects were randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 48 weeks in conjunction with diet and exercise.
  - At the 24-week interim analysis, the readout parameters are expected to include weight loss as measured by the relative (percent) change in body weight at 24 weeks compared to baseline, serum lipid profiles, adverse events, vital signs, glucose control and study discontinuations.
- *Initiation of Phase 2b NASH trial expected mid-2023*
  - This Phase 2b biopsy-driven NASH trial will be conducted at approximately 60 sites in the U.S., with Dr. Stephen Harrison, Medical Director, Pinnacle Research, and Adjunct Professor of Medicine, Oxford University, who led our 12-week NAFLD trial and 12-week extension trials, serving as the principal investigator.
  - The key endpoints will be NASH resolution and fibrosis improvement after 24 weeks of treatment.
  - The trial is expected to commence mid-2023 with top-line results expected in the first half of 2025.

HepTcell™

- *Enrollment in the Phase 2 clinical trial in chronic hepatitis B is over 90% complete*
  - The trial was designed to enroll approximately 80 subjects with inactive chronic hepatitis B randomized 1:1 to HepTcell or placebo.
  - Key endpoints include virological markers of hepatitis B infection.
  - Data readout is expected in the first half of 2024 after all subjects complete the 6-month course of treatment.

Patents

- On January 3, 2023, the United States Patent and Trademark Office issued the patent "IMPROVED PEPTIDE PHARMACEUTICALS FOR TREATMENT OF NASH AND OTHER DISORDERS", patent number 11,541,028, with an expiry of no earlier than January 3, 2039. The patent claims the use of pemvidutide for treating fatty liver diseases including NAFLD and NASH.

Financial Results for the Three Months Ended December 31, 2022

- Altimmune had cash, cash equivalents and short-term investments totaling $184.9 million at December 31, 2022.
- Revenue was negligible for the three months ended December 31, 2022 compared to $3.3 million in the same period in 2021, as we are closing out the remaining government contracts due to the discontinuation of development activities for the T-COVID and NasoShield programs in 2021.
- Research and development expenses were $19.2 million for the three months ended December 31, 2022, compared to $20.2 million in the same period in 2021. The expenses for the quarter ended December 31, 2022 included $13.4 million in direct costs related to development activities for pemvidutide and $1.9 million in direct costs related to development activities for HepTcell.
- General and administrative expenses were consistent period-over-period at $3.8 million for each of the three months ended December 31, 2022 and 2021.
- Net loss for the three months ended December 31, 2022 was $21.7 million, or $0.43 net loss per share, compared to a net loss of $23.9 million, or $0.57 net loss per share, in the same period in 2021.

Conference Call Information:

Date:	Tuesday, February 28, 2023
Time:	8:30 am Eastern Time
Webcast:	To listen, the conference call will be webcast live on Altimmune's Investor Relations website at https://ir.altimmune.com/investors.
Dial-in:	To participate or dial-in, may register here to receive the dial-in numbers and unique PIN to access the call.

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. Glucagon is also recognized as having direct effects on hepatic fat metabolism, leading to rapid reductions in levels of liver fat. Pemvidutide incorporates the EuPortTM domain, a proprietary technology that increases its serum half-life for weekly dosing while likely slowing the entry of pemvidutide into the bloodstream, which may improve its tolerability.

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 Altimmune

Altimmune 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, Altimmune is developing HepTcell™, an immunotherapeutic designed to achieve a functional cure for chronic hepatitis B. For more information, please visit www.altimmune.com.

Follow @Altimmune, Inc. on LinkedIn
Follow @AltimmuneInc on Twitter

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 HepTcell trial and the Phase 2 obesity and NASH clinical trials of pemvidutide, 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 Altimmune, 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: 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 impact of liver fat content and demographics in the Phase 1b NAFLD study on the success of future trials; 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 most recent annual report on Form 10-K and our other filings with the SEC, which are available at www.sec.gov.

Investor & Media Contacts:

Rich Eisenstadt
Chief Financial Officer
Phone: 240-654-1450
reisenstadt@altimmune.com

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

	December 31,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 111,097	$ 190,301
Restricted cash	34	34
Total cash, cash equivalents and restricted cash	111,131	190,335
Short-term investments	73,783	—
Accounts receivable	173	429
Income tax and R&D incentive receivables	2,368	5,410
Prepaid expenses and other current assets	5,358	7,952
Total current assets	192,813	204,126
Property and equipment, net	1,081	1,448
Intangible assets, net	12,419	12,419
Other assets	615	872
Total assets	$ 206,928	$ 218,865
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,804	$ 2,034
Contingent consideration	—	6,090
Accrued expenses and other current liabilities	12,250	10,152
Total current liabilities	17,054	18,276
Other long-term liabilities	4,581	1,454
Total liabilities	21,635	19,730
Commitments and contingencies (Note 17)		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 49,199,845 and 40,993,768 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	5	4
Additional paid-in capital	568,399	497,342
Accumulated deficit	(377,884)	(293,171)
Accumulated other comprehensive loss, net	(5,227)	(5,040)
Total stockholders' equity	185,293	199,135
Total liabilities and stockholders' equity	$ 206,928	$ 218,865

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Revenues	$ (110)	$ 3,277	$ (68)	$ 4,410
Operating expenses:				
Research and development	19,179	20,185	70,538	74,541
General and administrative	3,805	3,777	17,134	15,413
Impairment loss on construction-in-progress	—	3,300	—	11,370
Total operating expenses	22,984	27,262	87,672	101,324
Loss from operations	(23,094)	(23,985)	(87,740)	(96,914)
Other income (expense):				
Interest expense	183	62	(8)	(5)
Interest income	1,468	115	2,870	203
Other income (expense), net	(217)	(81)	(32)	(374)
Total other income (expense), net	1,434	96	2,830	(176)
Net loss before income taxes	(21,660)	(23,889)	(84,910)	(97,090)
Income tax expense (benefit)	—	—	(197)	—
Net loss	(21,660)	(23,889)	(84,713)	(97,090)
Other comprehensive income — unrealized gain (loss) on short-term investments	76	—	(187)	4
Comprehensive loss	$ (21,584)	$ (23,889)	$ (84,900)	$ (97,086)
Net loss per share, basic and diluted	$ (0.43)	$ (0.57)	$ (1.81)	$ (2.35)
Weighted-average common shares outstanding, basic and diluted	50,026,686	41,705,563	46,926,349	41,283,498