

**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 17, 2021

ALTIMMUNE, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

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

001-32587
(Commission
File Number)

20-2726770
(IRS Employer
Identification No.)

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 17, 2021, Altimmune, Inc. (the “Company”) issued a press release announcing the Company’s financial results for its fiscal quarter ended March 31, 2021. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

A copy of the presentation that will be used during the conference call presenting the Company’s financial results for the quarter ended March 31, 2021 is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information included in this Current Report on Form 8-K (including Exhibits 99.1 and 99.2 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 Exhibits 99.1 and 99.2 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 May 17, 2021
99.2	Presentation of Altimmune, Inc. dated May 17, 2021

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/ Will Brown

Name: Will Brown

Title: Chief Financial Officer

Dated May 17, 2021

Altimmune Announces First Quarter 2021 Financial Results and Provides a Corporate Update

*Data Readouts from Phase 1 AdCOVID™ and ALT-801 Clinical Trials Expected in June
Approximately \$227 Million in Cash and Short-Term Investments to Advance Pipeline*

GAITHERSBURG, MD, -- May 17, 2021 -- Altimmune, Inc. (Nasdaq: ALT), a clinical-stage biopharmaceutical company, today announced financial results for the three months ending March 31, 2021 and provided a corporate update.

"With AdCOVID™, our single-dose intranasal vaccine candidate for COVID-19 and ALT-801, our GLP-1/glucagon dual agonist candidate for non-alcoholic steatohepatitis (NASH) now advancing in the clinic, 2021 has the potential to be a data-rich period for the Company," remarked Vipin K. Garg, Ph.D., President and Chief Executive Officer at Altimmune. "We anticipate data readouts from both of these clinical trials in June. If the data from the AdCOVID Phase 1 trial are positive, we plan to quickly transition into a comprehensive global Phase 2 clinical development program. We strongly believe that a vaccine candidate like AdCOVID, which can be administered via a simple nasal spray along with what we hope will be an excellent safety and tolerability profile, could become an important tool for the global COVID-19 vaccination effort."

Dr. Garg continued, "ALT-801 is also progressing as planned through its first-in-human clinical trial in Australia and we anticipate 6-week data to be available later this quarter. We are excited about the potential of ALT-801, and hope that clinical studies will show ALT-801 can deliver similar therapeutic benefits to current GLP-1 based treatment options in development but without the GI intolerance that leads to treatment discontinuation. The NASH opportunity, together with a potential indication in obesity, could be very large for ALT-801 and early clinical success could have a dramatic effect on Altimmune's growth."

Recent Highlights:

AdCOVID, a novel, needle-free, intranasal vaccine candidate for COVID-19

- *Enrollment target met in amended AdCOVID Phase 1 clinical trial evaluating the safety and immunogenicity of AdCOVID in healthy volunteers*
 - The Phase 1 trial will measure systemic antibody responses including serum neutralizing antibody, T cell responses and mucosal IgA, a measure of mucosal immunity in the nasopharyngeal cavity
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- The study protocol was amended to reduce the number of adult subjects to approximately 80. The amendment was necessary due to the widespread availability of authorized vaccines. The final sample size of the study is comparable to the number of participants in Phase 1 studies of the U.S. authorized vaccines
- A topline data readout is anticipated in June 2021
- *Progressed development of adapted AdCOVID vaccine candidates targeting emerging SARS-CoV-2 variants*
 - Initiated preclinical evaluation of AdCOVID vaccine candidates targeting E484K variants, including P.1, B.1.351 and B.1.617
 - Initiation of a Phase 2 trial with a variant AdCOVID vaccine candidate expected in Q4 2021
- *Expanded manufacturing capabilities through an agreement with Lonza to commission a dedicated manufacturing suite for clinical and potential future commercial supply*
 - Complements and extends existing network of strategic manufacturing partners, building extra capacity and redundancy into the AdCOVID manufacturing effort
 - Supports manufacturing of clinical supply material for potential late-stage clinical trials and commercial scale
- *Announced new data from preclinical studies conducted in collaboration with the University of Alabama at Birmingham (UAB)*

In these preclinical studies, a single intranasal dose of AdCOVID provided:

 - 100% protection against a lethal challenge from the SARS-CoV-2 virus, with 1000-fold reduction of replicating virus in the nasal cavity and respiratory tract following infection with SARS-CoV-2
 - Sterilizing immunity, i.e., undetectable levels of infectious virus in the lungs, believed to be essential to fully block viral transmission
 - Long-lived systemic and mucosal immune responses, which were essentially unchanged over 6 months
- *Established plans for a robust Phase 2 clinical development program, which is anticipated to include:*
 - A multi-national study in adults 18 years of age and older in regions where vaccine access has been limited
 - An evaluation of AdCOVID as a potential booster for previously-infected and vaccinated individuals using a parental and P.1 variant AdCOVID vaccine
 - An age-based de-escalation study in children and adolescents
 - A study evaluating safety and immunogenicity in mother-infant pairs

ALT-801, a novel GLP-1/glucagon dual agonist candidate for NASH

- *Progressed ongoing Phase 1 clinical trial of ALT-801 in Australia*
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- Completed enrollment in the single ascending dose (SAD) phase and 3 planned cohorts of multiple ascending dose (MAD) phase of the trial, with 6-week data anticipated in June 2021, and 12-week data anticipated in Q3 2021
- Plans to commence a 52-week, Phase 2, biopsy-trial based on NASH endpoints in early 2022
- Anticipated mid-year IND filing to initiate U.S. NASH studies
- *Potential filing of a second IND for an obesity indication in 2H 2021*
 - The filing of a second IND in obesity in 2H 2021 is being evaluated, with the final decision based on the weight loss data from the upcoming Phase 1 trial readout

Other programs

- Continued progress in Phase 1/2 clinical trial of T-COVID, a therapeutic candidate for the treatment of SARS-CoV-2 and other respiratory infections, and a Phase 2 clinical trial of HepTcell, an immunotherapeutic candidate for the treatment of chronic hepatitis B

Financial Results for the Three Months Ended March 31, 2021

- Altimune had cash, cash equivalents and short-term investments totaling \$226.5 million at March 31, 2021 compared to \$216.0 million at December 31, 2020. The increase is primarily attributable to \$34.2 million of net receipts during the quarter due to its utilization of the at-the-market offering program, partially offset by \$19.6 million of cash used for operating activities.
- Revenue was \$0.8 million for the three months ended March 31, 2021 compared to \$2.2 million in the prior period, a decrease of \$1.4 million. The change in revenue quarter over quarter was primarily due to a decrease of \$2.0 million in BARDA revenue during the current period due to the timing of clinical trials and development activities for NasoShield, partially offset by \$0.5 million in revenue attributable to T-COVID.
- Research and development expenses were \$11.9 million for the three months ended March 31, 2021, compared to \$7.2 million in the prior period, representing an increase of \$4.7 million. The change was primarily the result of increased expenses of \$5.4 million related to development activities for the Company's COVID-19 programs, partially offset by a decrease of \$1.5 million resulting from a decrease in the fair value of contingent consideration liability connected with the acquisition and development of ALT-801.
- General and administrative expenses were \$3.8 million for the three months ended March 31, 2021 compared to \$2.3 million in the prior period, an increase of \$1.5 million. The increase during the quarter is primarily due to increased stock compensation expense and additional labor related costs.
- Net loss for the three months ended March 31, 2021 was \$14.9 million, or \$0.38 net loss per share, compared to \$3.9 million in the prior period, or \$0.26 net loss per share. The difference in net loss is primarily attributable to higher research and development expenses and general and administrative expenses.



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Conference Call Information

Date: Monday, May 17, 2021
Time: 8:30 am Eastern Time
Domestic Dial-in: 877-423-9813
International Dial-in: 201-689-8573
Conference ID: 13719206
Webcast: <http://public.viavid.com/index.php?id=144634>

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.alimmune.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 Altimimmune

Altimimmune is a clinical stage biopharmaceutical company focused on developing intranasal vaccines, immune modulating therapies and treatments for liver disease. Our diverse pipeline includes proprietary intranasal vaccines for COVID-19 (AdCOVID™), anthrax (NasoShield™) and influenza (NasoVAX™); an intranasal immune modulating therapeutic for COVID-19 (T-COVID™); and next generation peptide therapeutics for NASH (ALT-801) and chronic hepatitis B (HepTcell™). For more information on Altimimmune, please visit www.alimmune.com.

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Follow @AltimuneInc 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 readout from the AdCOVID Phase 1 clinical trial in June 2021, the potential start of the AdCOVID Phase 2 clinical program in Q2 2021, the potential immunization effects of AdCOVID, the potential of AdCOVID to block SARS-CoV-2 transmission, the shipping and storage requirements for AdCOVID, our ability to manufacture AdCOVID for our clinical trials and commercial needs, the expected completion of the single ascending dose (SAD) and multiple ascending dose (MAD) phases of the ALT-801 study, with 6-week data expected in June 2021 and 12-week data in Q3 2021, the anticipated mid-year IND filing for ALT-801, the commencement of a 52-week, Phase 2, biopsy-trial based on NASH endpoints in early 2022, the HepTcell Phase 2 clinical efficacy trial data readout anticipated in 1H 2022, the prospects for regulatory approval of our product candidates and 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 Altimimmune,



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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 due to 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 and commercial supply on the timelines anticipated; the Company’s ability to secure manufacturing approval from its SARS-CoV-2 cell licensor 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, 2020 filed with the SEC, which is available at www.sec.gov.

Investor & Media Contacts:

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ALTIMMUNE, INC.
CONSOLIDATED BALANCE SHEETS

	March 31, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 149,932,387	\$ 115,917,80
Restricted cash	34,174	34,17
Total cash, cash equivalents and restricted cash	149,966,561	115,951,96
Short-term investments	76,574,768	100,005,55
Accounts receivable	4,801,428	4,610,20
Tax refund receivable	7,898,067	7,762,79
Prepaid expenses and other current assets	5,950,999	1,926,67
Total current assets	245,191,823	230,257,20
Property and equipment, net	5,198,052	1,056,92
Right of use asset	866,336	903,82
Intangible assets, net	12,879,247	12,823,84
Other assets	115,300	73,41
Total assets	<u>\$ 264,250,758</u>	<u>\$ 245,115,21</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 418,243	\$ 612,25
Accrued expenses and other current liabilities	9,405,649	11,408,15
Total current liabilities	9,823,892	12,020,42
Contingent consideration	6,270,000	5,390,00
Other long-term liabilities	1,719,438	1,828,44
Total liabilities	17,813,330	19,238,89
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized;		
38,257,180 and 37,142,946 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	3,810	3,66
Additional paid-in capital	462,417,706	417,337,74
Accumulated deficit	(210,944,707)	(186,420,56)
Accumulated other comprehensive loss, net	(5,039,381)	(5,044,51)
Total stockholders' equity	246,437,428	225,876,32
Total liabilities and stockholders' equity	<u>\$ 264,250,758</u>	<u>\$ 245,115,21</u>



ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Three Months Ended March 31,	
	2021	2020
Revenues	\$ 837,516	\$ 2,212,694
Operating expenses:		
Research and development	11,877,900	7,187,531
General and administrative	3,821,420	2,331,917
Total operating expenses	<u>15,699,320</u>	<u>9,519,448</u>
Loss from operations	<u>(14,861,804)</u>	<u>(7,306,754)</u>
Other income (expense):		
Interest expense	(11,671)	(1,885)
Interest income	42,499	151,569
Other (expense) income, net	<u>(33,132)</u>	<u>25,542</u>
Total other (expense) income, net	<u>(2,304)</u>	<u>175,226</u>
Net loss before income tax benefit	<u>(14,864,108)</u>	<u>(7,131,528)</u>
Income tax benefit	—	3,245,879
Net loss	<u>(14,864,108)</u>	<u>(3,885,649)</u>
Other comprehensive income (loss) – unrealized gain (loss) on investments	5,136	(32,435)
Comprehensive loss	<u>\$ (14,858,972)</u>	<u>\$ (3,918,084)</u>
Net loss per share, basic and diluted	<u>\$ (0.38)</u>	<u>\$ (0.26)</u>
Weighted-average common shares outstanding, basic and diluted	<u>38,914,990</u>	<u>15,110,585</u>



NASDAQ: ALT

First Quarter 2021 Results

Corporate Update & Financial Results
May 17, 2021

FORWARD-LOOKING STATEMENTS

Safe-Harbor Statement

This presentation has been prepared by Altimimmune, Inc. ("we," "us," "our," "Altimimmune" or the "Company") and includes certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the timing of clinical development and funding milestones for our clinical assets as well as statements relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters, and the prospects for commercializing or selling any product or drug candidates. In addition, when or if used in this presentation, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to 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 due to the COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, the timing and reliability of the results of the studies relating to human safety and possible adverse effects resulting from the administration of the Company's product candidates; our lack of financial resources and access to capital; clinical trials and the commercialization of proposed product candidates (such as marketing, regulatory, product liability, supply, competition, dependence on third parties and other risks); the timing of regulatory applications and the regulatory approval process; dependence on intellectual property; the Company's BARDA contract and other government programs, reimbursement and regulation. 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 reports on Form 10-K and quarterly reports on Form 10-Q filed with the SEC, which are available at www.sec.gov. The statements made herein speak only as of the date stated herein, and any forward-looking statements contained herein are based on assumptions that the Company believes to be reasonable as of this date. The Company undertakes no obligation to update these statements as result of new information or future events.

AGENDA

Corporate Update

Vipin K. Garg, Ph.D. – President and Chief Executive Officer

Preclinical Update

Scot Roberts, Ph.D. – Chief Scientific Officer

Clinical Update

Scott Harris, M.D. – Chief Medical Officer

Q1 Financial Update

Will Brown, CPA – Chief Financial Officer

Q&A

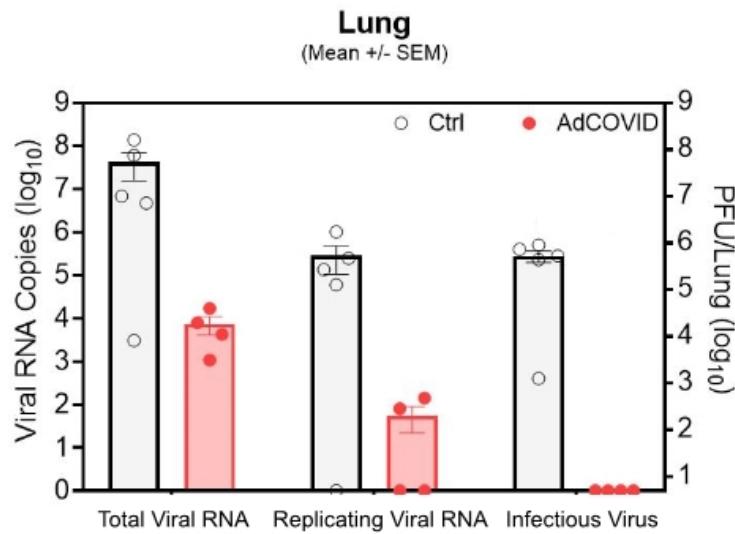




AdCOVID
Preclinical Update

AdCOVID PROVIDES STERILIZING IMMUNITY IN MICE

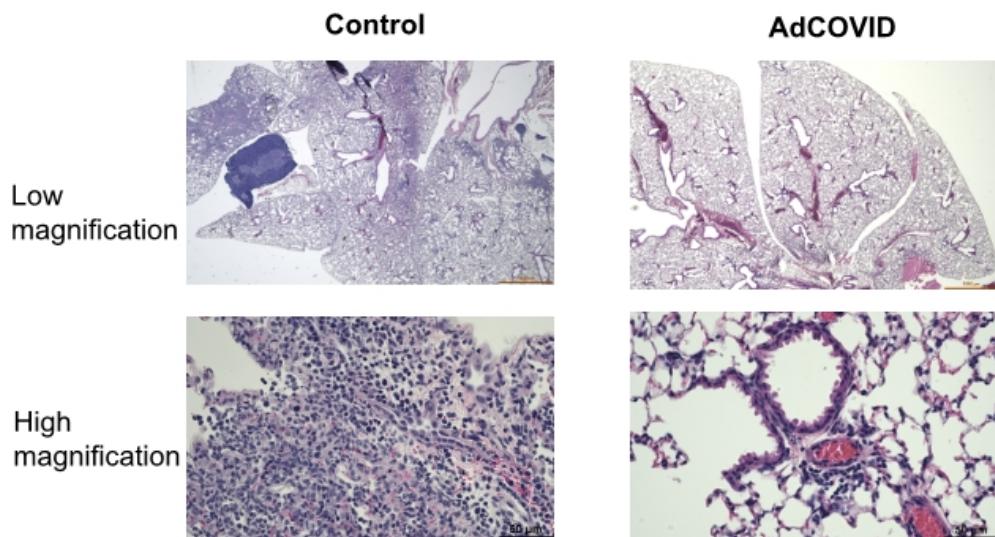
- Single intranasal dose of AdCOVID administered 28 days prior to SARS-CoV-2 challenge
- Heavy viral RNA burden reduced ~1000-fold over non-vaccinated controls
- Infectious virus undetectable in lungs of AdCOVID vaccinated mice ($\geq 50,000$ -fold reduction in PFU over non-vaccinated controls)



PFU: plaque-forming units; Ctrl: unvaccinated controls



SINGLE DOSE AdCOVID PROTECTS AGAINST LUNG DISEASE IN MICE





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**AdCOVID
Clinical Update**

AMENDED ADCOVID PHASE 1 STUDY DESIGN

- Approximately 80 subjects randomized 5:1 to receive one or two doses of AdCOVID or placebo
- Three dose groups
 - Low dose— 1×10^{10} vp
 - Medium dose— 3×10^{10} vp
 - High dose— 1×10^{11} vp
- Immunogenicity readouts will include neutralizing Ab, anti-spike IgG, and anti-spike IgA (mucosal immunogenicity) measured 28 days after the first and second doses
- Enrollment target met, and topline results expected June 2021
- T cell readouts expected to follow in 4-6 weeks



KEY STUDIES TO SUPPORT AdCOVID TARGET PRODUCT PROFILE

Target Product Profile

- Boosts natural immune response to wild-type and variant viruses in previously infected but unvaccinated individuals
- Boosts immune response to wild-type and variant viruses in vaccinated individuals
- Safe and well-tolerated in children down to 2 years of age
- Safe for use in pregnant and breast-feeding women

Key Anticipated Phase 2 Trials

- Naïve and previously-infected populations in Low-Access Countries
- Revaccination with parental and variant vaccines in previously vaccinated individuals
- Age-based de-escalation study in young children and adolescents
- Maternal immunization study





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**ALT-801
Clinical Update**

ALT-801 PHASE 1 TRIAL UPDATE

- Phase 1 study is advancing to study readout
 - Enrollment completed in the single ascending dose (SAD) phase and the 3 planned cohorts of multiple ascending dose (MAD) phase of the trial
 - 6-week data anticipated in June 2021; 12-week data anticipated in Q3 2021
- Anticipate mid-year IND filing to initiate NASH studies in the US
- A 52-week, Phase 2, biopsy-trial based on NASH endpoints is expected to commence in early 2022

ALT-801 – POTENTIAL IND FILING FOR OBESITY IN 2H 2021

- Novo Nordisk (semaglutide) and Lilly (tirzepatide) have executed successful Phase 3 programs; these have de-risked the obesity space previously occupied by unsafe and ineffective drugs
- GI intolerance has been the Achilles heel for GLP-1 based treatments, with side effects leading to treatment discontinuation
- If the impressive weight loss and tolerability of ALT-801 in preclinical studies translate to the clinical setting, ALT-801 could become a best-in-class treatment in this indication
- The filing of a 2nd IND in obesity in 2H 2021 is being evaluated, with the final decision based on the upcoming Phase 1 trial readout





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First Quarter 2021 Results

Corporate Update & Financial Results

May 17, 2021

