

June 1, 2021



Immunovant Provides Corporate Updates and Reports Financial Results for the Quarter and Fiscal Year Ended March 31, 2021

- Immunovant plans to resume clinical development of IMVT-1401 in Myasthenia Gravis (MG) and Warm Autoimmune Hemolytic Anemia (WAIHA) as well as initiate two additional mid-to-late stage studies in the next year
- Program-wide data review suggests that IMVT-1401 has a broader therapeutic window than previously anticipated and that lipid elevations are predictable, manageable, and appear to be driven by reductions in albumin
- Cash balance of approximately \$400 million as of March 31, 2021

NEW YORK, June 01, 2021 (GLOBE NEWSWIRE) -- Immunovant, Inc. (Nasdaq: IMVT), a clinical-stage biopharmaceutical company focused on enabling normal lives for people with autoimmune diseases, today provided a corporate update and reported financial results for its fiscal fourth quarter and fiscal year ended March 31, 2021.

“Following a program-wide data review, we remain confident in our plan to develop IMVT-1401 across a broad range of autoimmune indications. We look forward to constructive dialogue with regulatory agencies and plan to resume clinical development of IMVT-1401, including in a potentially pivotal trial in Myasthenia Gravis and in a phase two study of Warm Autoimmune Hemolytic Anemia in late 2021 or early 2022. We also plan to initiate two additional studies in the next twelve months after discussions with regulators.” said Pete Salzmann, M.D., Chief Executive Officer of Immunovant.

In a program-wide review, the company observed increases in LDL in multiple studies that were consistent, dose-related, and appear to be driven by reductions in albumin levels. No relationship to levels of thyroid hormone was observed. The increases in LDL and reductions in albumin were reversible upon cessation of dosing, and no major adverse cardiovascular events have been reported to date. Consultations with expert medical advisors have reinforced the company’s belief that Immunovant will be able to manage these changes within its development program via monitoring and management criteria, adjustments to dosing, and individualized anti-lipid therapy as appropriate.

Dr. Salzmann noted: “While both the 340mg and 680mg weekly doses demonstrated substantial reductions in IgG, the 255mg dose also achieved significant IgG reductions but without the same extent of undesired reductions in albumin or related increases in LDL.” IgG reductions in the Thyroid Eye Disease (TED) study ranged from 62% in 255mg to 80% in the 680mg arm. Dr. Salzmann continued: “These results present an opportunity for flexibility in dosing, dose intervals, and a lower-volume injection to explore in our future clinical trials.” Further, the company noted that in a post-hoc analysis of all patients who entered trials of IMVT-1401 on statins, only minimal LDL increases were seen across a variety of doses and

indications.

Pending agreement from regulatory agencies, Immunovant plans to return to the clinic and initiate a pivotal MG trial in late 2021 or early 2022 as well as resume its trial in WAIHA on a similar timeframe. The company plans to initiate at least two additional clinical studies over the next 12 months, including another pivotal trial in 2022.

As part of the company's data review, the Ph 2b TED study was unblinded and terminated prior to completion. While the trial showed clear biologic activity based on changes in IgG and pathologic autoantibodies, prematurely terminating the study resulted in inconclusive efficacy results. Forty-one subjects out of a planned seventy-seven reached the twelve-week primary endpoint. Efficacy data in this underpowered subset was more modest than the company had hoped and was not statistically significant on the primary endpoint. However, biologic effects, including a relationship between auto-antibodies and disease activity were observed that the company feels are encouraging with respect to treating TED. Immunovant plans to work with regulators and key opinion leaders on a design for a subsequent study and believes a phase 2 trial rather than a pivotal study is likely to be the appropriate next step in the development of IMVT-1401 in this therapeutic area.

Immunovant also announced today the appointment of William (Bill) Macias, MD PhD, as Chief Medical Officer. He succeeded Rita Jain, M.D., who informed the company of her plans to step down from her position as Chief Medical Officer to pursue another opportunity. Dr. Macias brings over 27 years of pharmaceutical experience to Immunovant, including industry-leading experience in early, mid, and late phase development. "We are thrilled to consolidate full scientific and development leadership under Bill," said Dr. Salzmann. "His impressive breadth of experience and proven track record of clinical development in numerous therapeutic areas fits very well with the potential of IMVT-1401 across multiple indications." He added, "I also want to extend my appreciation to Rita for her contributions to Immunovant during her tenure."

Dr. Macias previously served as a Distinguished Medical Fellow and a member of senior management at Eli Lilly, where he worked for over twenty years. At Lilly, he led multiple global clinical development programs leading to submission and approval of medications in immunology, cardiology, and other therapeutic areas. For the past three years, Bill has worked with many global biotechnology companies as a senior medical consultant providing company strategy and drug development leadership. "I am incredibly excited to be part of Immunovant," said Dr. Macias. "The anti-FcRn mechanism is unique within Immunology, and IMVT-1401 holds the potential to benefit many patients across a broad range of indications."

Immunovant will host a conference call on Tuesday, June 1 at 8:00 am EDT. Following prepared remarks, the call will include a live question-and-answer session for the investment community. To access the webcast, please visit Immunovant's website at www.immunovant.com. Participants may also dial in using the numbers provided below:

Toll Free: 1-877-407-9039

Toll/International: 1-201-689-8470

An archived webcast recording will be available on the Immunovant's website for a limited time.

Financial Highlights for Fiscal Fourth Quarter and Fiscal Year Ended March 31, 2021:

R&D Expenses: Research and development expenses were \$18.6 million for the three months ended March 31, 2021, compared to \$14.2 million for the three months ended March 31, 2020. Research and development expenses were \$68.6 million for the year ended March 31, 2021, compared to \$47.9 million for the year ended March 31, 2020. The year-over-year increase was primarily due to increases in contract manufacturing costs, driven by the expansion of clinical trial programs for the treatment of autoimmune diseases, and costs related to non-clinical and clinical studies. Other increases include higher personnel-related expenses (including stock-based compensation expense) due to higher headcount to support clinical operations and increased professional services.

G&A Expenses: General and administrative expenses were \$10.3 million for the three months ended March 31, 2021, compared to \$6.3 million for the three months ended March 31, 2020. General and administrative expenses were \$39.5 million for the year ended March 31, 2021, compared to \$18.2 million for the year ended March 31, 2020. The year-over-year increase was primarily due to higher personnel-related expenses (including stock-based compensation), due to higher headcount. Other increases include higher legal, professional, and other administrative costs to support our personnel growth and operations as a public company.

Net Loss: Net loss was \$28.2 million (\$0.29 per common share) for the three months ended March 31, 2021, compared to \$20.6 million (\$0.38 per common share) for the three months ended March 31, 2020. Net loss was \$107.4 million (\$1.22 per common share) for the year ended March 31, 2021, compared to \$66.4 million (\$1.54 per common share) for the year ended March 31, 2020. Net loss for the year ended March 31, 2021 and 2020 included \$18.8 million and \$7.0 million, respectively, related to non-cash stock-based compensation expense.

Common Stock: As of March 31, 2021, there were 97,971,243 shares of common stock issued and outstanding.

About Immunovant, Inc.

Immunovant, Inc. is a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases. Immunovant is developing IMVT-1401, a novel, fully human anti-FcRn monoclonal antibody, as a subcutaneous injection for the treatment of autoimmune diseases mediated by pathogenic IgG antibodies.

Forward-Looking Statements

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as “may,” “might,” “will,” “would,” “should,” “expect,” “believe,” “estimate,” and other similar expressions are intended to identify forward-looking statements. Such forward looking statements include Immunovant’s plan to develop IMVT-1401 across a broad range of autoimmune indications; Immunovant’s plan to return to the clinic and initiate a pivotal MG trial in late 2021 or early 2022, as well as resume its trial in WAIHA on a similar timeframe; Immunovant’s plans to initiate 2-3 additional clinical studies over the next 12 months, including another pivotal trial in 2022, after discussions with

regulators; Immunovant’s ability to manage increases in LDL and reductions in albumin within its development program via monitoring and management criteria, adjustments to dosing, and individualized anti-lipid therapy as appropriate; and the potential for a phase two trial in TED. All forward-looking statements are based on estimates and assumptions by Immunovant’s management that, although Immunovant believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Immunovant expected. Such risks and uncertainties include, among others: initial results or other preliminary analyses or results of early clinical trials may not be predictive final trial results or of the results of later clinical trials; the timing and availability of data from clinical trials; the timing of discussions with regulatory agencies, as well as regulatory submissions and potential approvals; the continued development of Immunovant’s product candidates, including the timing of the commencement of additional clinical trials and resumption of current trials; Immunovant’s scientific approach, clinical trial design, indication selection and general development progress; future clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release; any product candidates that Immunovant develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; Immunovant’s product candidates may not be beneficial to patients, or even if approved by regulatory authorities, successfully commercialized; the potential impact of the ongoing COVID-19 pandemic on Immunovant’s clinical development plans and timelines; Immunovant’s business is heavily dependent on the successful development, regulatory approval and commercialization of its sole product candidate, IMVT-1401; Immunovant is at an early stage in development of IMVT-1401; and Immunovant will require additional capital to fund its operations and advance IMVT-1401 through clinical development. These and other risks and uncertainties are more fully described in Immunovant’s periodic and other reports filed with the Securities and Exchange Commission (SEC), including in the section titled “Risk Factors” in Immunovant’s Annual Report on Form 10-K for the year ended March 31, 2021 filed with the SEC on June 1, 2021. Any forward-looking statement speaks only as of the date on which it was made. Immunovant undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

IMMUNOVANT, INC.

Consolidated Statements of Operations

(In thousands, except share and per share data)

Three Months Ended		Years Ended March 31,	
March 31,		2021	
2021	2020	2021	2020
(Unaudited)	(Unaudited)		

Operating expenses:

Research and development (includes \$3,008 and \$447 of stock-based compensation expense for the three months ended March 31, 2021 and 2020 and \$7,033 and \$3,130 for the years ended March 31, 2021 and 2020, respectively) (1)	\$ 18,615	\$ 14,168	\$ 68,604	\$ 47,927
General and administrative (includes \$2,480 and \$1,393 of stock-based compensation expense for the three months ended March 31, 2021 and 2020 and \$11,789 and \$3,833 for the years ended March 31, 2021 and 2020, respectively) (2)	10,302	6,315	39,513	18,151
Total operating expenses	<u>28,917</u>	<u>20,483</u>	<u>108,117</u>	<u>66,078</u>
Interest expense	—	—	—	625
Other (income) expense, net	<u>(680)</u>	<u>127</u>	<u>(328)</u>	<u>(412)</u>
Loss before (benefit) provision for income taxes	<u>(28,237)</u>	<u>(20,610)</u>	<u>(107,789)</u>	<u>(66,291)</u>
(Benefit) provision for income taxes	(79)	(59)	(358)	97
Net loss	<u><u>\$ (28,158)</u></u>	<u><u>\$ (20,551)</u></u>	<u><u>\$ (107,431)</u></u>	<u><u>\$ (66,388)</u></u>
Net loss per common share — basic and diluted ⁽³⁾	<u><u>\$ (0.29)</u></u>	<u><u>\$ (0.38)</u></u>	<u><u>\$ (1.22)</u></u>	<u><u>\$ (1.54)</u></u>
Weighted average shares outstanding — basic and diluted ⁽³⁾	97,971,243	54,655,376	87,756,513	43,199,191

(1) Includes \$164 and \$7 of costs allocated from Roivant Sciences Ltd. for the three months ended March 31, 2021 and 2020 and \$340 and \$159 for the years ended March 31, 2021 and 2020 respectively.

(2) Includes \$658 and \$380 of costs allocated from Roivant Sciences Ltd. for the three months ended March 31, 2021 and 2020 and \$1,180 and \$1,381 for the years ended March 31, 2021 and 2020, respectively.

(3) Retroactively restated for the reverse recapitalization.

IMMUNOVANT, INC.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31,	
	2021	2020
Assets		
Current assets:		
Cash	\$ 400,146	\$ 100,571
Prepaid expenses	8,312	5,460
Income tax receivable	548	36
Value-added tax receivable	—	3,009
Total current assets	409,006	109,076
Operating lease right-of-use assets	3,282	—
Property and equipment, net	201	65
Deferred offering costs	—	246
Total assets	\$ 412,489	\$ 109,387
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,432	\$ 1,190
Accrued expenses	15,160	10,938
Current portion of operating lease liabilities	1,179	—
Due to Roivant Sciences Ltd.	—	3,190
Total current liabilities	18,771	15,318
Operating lease liabilities, net of current portion	2,238	—
Total liabilities	21,009	15,318
Commitments and contingencies		
Stockholders' equity: ⁽¹⁾		
Series A preferred stock, par value \$0.0001 per share, 10,000 shares authorized, issued and outstanding at March 31, 2021 and March 31, 2020	—	—
Preferred stock, par value \$0.0001 per share, 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2021 and March 31, 2020	—	—
Common stock, par value \$0.0001 per share, 500,000,000 shares authorized, 97,971,243 shares issued and outstanding at March 31, 2021 and 500,000,000 shares authorized, 56,455,376 shares issued and 54,655,376 shares outstanding at March 31, 2020	10	5
Additional paid-in capital	590,425	185,306
Accumulated other comprehensive loss	(298)	(16)

Accumulated deficit	(198,657)	(91,226)
Total stockholders' equity	391,480	94,069
Total liabilities and stockholders' equity	\$ 412,489	\$ 109,387

(1) Retroactively restated for the reverse recapitalization.

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Source: Immunovant