



vTv Therapeutics Announces 2021 First Quarter Financial Results and Provides Corporate Update

05/05/21

Awarded Breakthrough Therapy designation for TTP399 for the treatment of type 1 diabetes

Initiated two phase 1 clinical studies, mechanistic study of TTP399 and multiple ascending dose study of HPP737

HIGH POINT, N.C., May 05, 2021 (GLOBE NEWSWIRE) -- [vTv Therapeutics Inc.](https://www.vtvtherapeutics.com) (Nasdaq:VTVT) today reported financial results for the first quarter ended March 31, 2021, and provided an update on the progress of its clinical programs.

"The vTv team continued to build on the clinical success of our type 1 diabetes program during the quarter by obtaining Breakthrough Therapy designation from the FDA for TTP399 and by initiating a phase 1 study to understand TTP399's impact on ketoacidosis. The FDA's grant of Breakthrough is an acknowledgment of the significant unmet need for patients with type 1 diabetes, and the encouraging clinical results we have generated to date," said Steve Holcombe, president and CEO, vTv Therapeutics. "We look forward to working closely with the FDA to optimize the development pathway for TTP399 to bring this potential treatment to patients with type 1 diabetes as quickly as possible."

Recent Achievements and Outlook

Type 1 Diabetes

- **Breakthrough Therapy Designation.** As announced in April, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for TTP399 as an adjunctive therapy to insulin for the treatment of type 1 diabetes. Breakthrough Therapy designation is intended to expedite the development and review of a drug candidate that is planned for the treatment of a serious or life-threatening disease where initial clinical evidence indicates that the drug may demonstrate a substantial improvement over existing therapies on one or more clinically significant endpoints.
- **Mechanistic Study of Ketoacidosis with TTP399.** The Company began dosing patients in a mechanistic study of TTP399 in people with type 1 diabetes to determine the impact of TTP399 on ketone body formation during a period of acute insulin withdrawal. vTv expects to report topline results from the mechanistic study in the third quarter of 2021.
- **Pivotal Study Planning.** The Company is planning to initiate the first of two pivotal, placebo-controlled, six-month clinical trials of TTP399 in subjects with type 1 diabetes in the fourth quarter of 2021. The current study designs will be shared with the FDA for its input and advice as part of the collaborative process enabled by the Breakthrough Therapy designation.

Psoriasis

- **Multiple Ascending Dose Study with HPP737.** The Company began dosing healthy subjects in a phase 1 multiple ascending dose study to assess the safety, tolerability, and pharmacokinetic profile of HPP737, an oral PDE4 inhibitor. This phase 1 study is expected to report topline results in the third quarter and will inform dose selection for a planned phase 2 study in psoriasis.

License Partner Updates

- **Reneo Pharmaceuticals Completes Initial Public Offering.** We congratulate our licensee, Reneo Pharmaceuticals, Inc. (Nasdaq: RPHM), for successfully completing an initial public offering in April. The Company is party to a license agreement with Reneo for its lead asset REN001, which Reneo is currently developing in three rare genetic diseases: primary mitochondrial myopathies, long-chain fatty acid oxidation disorders, and glycogen storage disease type V (McArdle disease).

First Quarter 2021 Financial Results

- **Cash Position:** The Company's cash position as of March 31, 2021, was \$8.4 million compared to \$5.7 million as of December 31, 2020.
- **Revenue:** Revenue for the first quarter of 2021 was \$1.0 million and was \$6.4 million for the fourth quarter of 2020. The revenue for the first quarter was non-cash and related to the recognition of revenue pertaining to the Huadong license agreement. The revenue for the fourth quarter was primarily attributable to the upfront consideration, consisting of cash and an equity interest, received in connection with the Company's license agreement with Anteris Bio.
- **R&D Expenses:** Research and development expenses were \$3.1 million and \$2.5 million for the three months ended March 31, 2021 and December 31, 2020, respectively. This increase of \$0.6 million was driven primarily by the increase in spending for our study of HPP737 in psoriasis.
- **G&A Expenses:** General and administrative expenses were consistent between periods at \$2.2 million and \$2.0 million for the three months ended March 31, 2021 and December 31, 2020, respectively.
- **Net (Loss)/Income Before Non-Controlling Interest:** Net loss before non-controlling interest was \$5.9 million for the first quarter of 2021 compared to net income of \$1.6 million for the fourth quarter of 2020.
- **Net (Loss)/Income Per Share:** Diluted net loss per share was (\$0.08) for the three months ended March 31, 2021 compared to a diluted net income per share of \$0.02 for the three months ended December 31, 2020, based on weighted-average diluted shares of 56.5 million and 74.4 million for the three-month periods ended March 31, 2021 and December 31, 2020, respectively. Non-GAAP net loss per fully exchanged share was (\$0.09) for the three months ended March 31, 2021 compared to a net income per fully exchanged share of \$0.02 at December 31, 2020, based on non-GAAP fully exchanged weighted-average shares of 79.6 million and 74.4 million for the three months ended March 31, 2021 and December 31, 2020, respectively.

vTv Therapeutics Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2021	December 30, 2020
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,449	\$ 5,747
Accounts receivable, net	2	158
Prepaid expenses and other current assets	710	939
Current deposits	60	371
Total current assets	9,221	7,215
Property and equipment, net	344	367
Operating lease right-of-use assets	464	482
Long-term investments	6,725	6,725
Total assets	\$ 16,754	\$ 14,789
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,965	\$ 6,120
Operating lease liabilities	162	155
Current portion of contract liabilities	35	31
Current portion of notes payable	—	84
Total current liabilities	5,162	6,390
Contract liabilities, net of current portion	18	1,009
Operating lease liabilities, net of current portion	633	676
Warrant liability, related party	4,519	2,871
Other liabilities	50	50
Total liabilities	10,382	10,996
Commitments and contingencies		
Redeemable noncontrolling interest	62,647	83,895
Stockholders' deficit:		

Class A Common Stock	576	541
Class B Common Stock	232	232
Additional paid-in capital	217,647	209,161
Accumulated deficit	(274,730)	(290,036)
Total stockholders' deficit attributable to vTv Therapeutics Inc.	(56,275)	(80,102)
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	\$ 16,754	\$ 14,789

vTv Therapeutics Inc.
Condensed Consolidated Statements of Operations - Unaudited
(in thousands, except per share data)

	Three Months Ended	
	March 31, 2021	December 31, 2020
Revenue	\$ 987	\$ 6,399
Operating expenses:		
Research and development	3,103	2,534
General and administrative	2,164	2,035
Total operating expenses	5,267	4,569
Operating (loss)/income	(4,280)	1,830
Interest income	1	—
Interest expense	—	(67)
Other expense, net	(1,648)	(156)
Loss before income taxes and noncontrolling interest	(5,927)	1,607
Income tax provision	15	—
Net loss before noncontrolling interest	(5,942)	1,607
Less: net (loss)/income attributable to noncontrolling interest	(1,701)	481
Net (loss)/income attributable to vTv Therapeutics Inc.	\$ (4,241)	\$ 1,126
Net (loss)/income attributable to vTv Therapeutics Inc. common shareholders	\$ (4,241)	\$ 1,126
Net (loss)/income per share:		
Basic net (loss)/income per share of vTv Therapeutics Inc. Class A Common Stock	\$ (0.08)	\$ 0.02
Diluted net (loss)/income per share of vTv Therapeutics Inc. Class A Common Stock	\$ (0.08)	\$ 0.02
Weighted average shares used in calculating:		
Basic net (loss)/income per share of vTv Therapeutics Inc. Class A Common Stock	56,472,535	51,133,609
Diluted net (loss)/income per share of vTv Therapeutics Inc. Class A Common Stock	56,472,535	74,397,085

vTv Therapeutics Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share data)

	Three Months Ended March 31,	
	2021	2020
	(Unaudited)	
Revenue	\$ 987	\$ 8
Operating expenses:		
Research and development	3,103	4,204
General and administrative	2,164	2,450
Total operating expenses	5,267	6,654
Operating loss	(4,280)	(6,646)
Interest income	1	12
Interest expense	—	(168)
Other expense, net	(1,648)	(363)
Loss before income taxes and noncontrolling interest	(5,927)	(7,165)
Income tax provision	15	—
Net loss before noncontrolling interest	(5,942)	(7,165)
Less: net loss attributable to noncontrolling interest	(1,701)	(2,441)

Net loss attributable to vTv Therapeutics Inc.	\$ (4,241)	\$ (4,724)
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (4,241)	\$ (4,724)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	\$ (0.08)	\$ (0.11)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	56,472,535	43,462,551

About vTv Therapeutics

vTv Therapeutics Inc. is a clinical-stage biopharmaceutical company focused on developing oral, small molecule drug candidates. vTv has a pipeline of clinical drug candidates led by programs for the treatment of type 1 diabetes and psoriasis. vTv's development partners are pursuing additional indications in type 2 diabetes, chronic obstructive pulmonary disease, renal disease, and primary mitochondrial myopathy.

Forward-Looking Statements

This release contains forward-looking statements, which involve risks and uncertainties. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and, in each case, their negative or other various or comparable terminology. All statements other than statements of historical facts contained in this release, including statements regarding the timing of our clinical trials, our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause our results to vary from expectations include those described under the heading "Risk Factors" in our Annual Report on Form 10-K and our other filings with the SEC. These forward-looking statements reflect our views with respect to future events as of the date of this release and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this release and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this release. We anticipate that subsequent events and developments will cause our views to change. Our forward-looking statements do not reflect the potential impact of any future acquisitions, merger, dispositions, joint ventures or investments we may undertake. We qualify all of our forward-looking statements by these cautionary statements.

Non-GAAP Financial Measures

To supplement our consolidated financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the U.S. ("GAAP"), we use non-GAAP adjusted net income/(loss) per fully exchanged share, which is a non-GAAP financial measure. Non-GAAP adjusted net loss per fully exchanged share adjusts the net loss attributable to vTv common shareholders for the impact of adjustments related to outstanding warrants, share-based compensation expense and the portion of net loss attributable to the noncontrolling interest. It also assumes the exchange of all the Class B common stock of vTv Therapeutics Inc. and an equal number of non-voting common units of vTv Therapeutics LLC ("vTv Units") for shares of Class A common stock of vTv Therapeutics Inc. We believe that this measure provides useful information to investors as it eliminates the variability of non-controlling interest resulting from the exchanges of Class B common stock and vTv Units into Class A common stock and other items of a non-cash nature. This measure is not intended to be considered in isolation or as a substitute for, or superior to, financial measures prepared and presented in accordance with GAAP.

The following is a reconciliation of non-GAAP adjusted net loss per fully exchanged share, basic and diluted to its most directly comparable GAAP measure, net loss per share of vTv Therapeutics Inc. Class A common stock, basic and diluted and the computation of the components of this non-GAAP measure:

	Three Months Ended	
	March 31, 2021	December 30, 2020
Numerator:		
Net (loss)/income attributable to vTv Therapeutics Inc. common shareholders	\$ (4,241)	\$ 1,126
Other expense - related party	(1,648)	(156)
Share-based compensation expense	436	272
Reallocation of net income attributable to noncontrolling interest from the assumed exchange of Class B shares ⁽¹⁾	(1,701)	481
Adjusted net (loss)/income before noncontrolling interest	\$ (7,154)	\$ 1,723
Denominator:		
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, diluted	56,472,535	74,397,085
Assumed exchange of Class B Common Stock ⁽¹⁾	23,094,137	—
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, diluted	79,566,672	74,397,085
Adjusted net (loss)/income per fully exchanged share, diluted	\$ (0.09)	\$ 0.02

	Three Months Ended March 31,	
	2021	2020
Numerator:		
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (4,241)	\$ (4,724)

Other expense - related party	(1,648)	(363)
Share-based compensation expense	436	380
Reallocation of net income attributable to noncontrolling interest from the assumed exchange of Class B shares ⁽¹⁾	(1,701)	(2,441)
Adjusted net loss before noncontrolling interest	<u>\$ (7,154)</u>	<u>\$ (7,148)</u>
Denominator:		
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, diluted	56,472,535	43,462,551
Assumed exchange of Class B Common Stock ⁽¹⁾	<u>23,094,137</u>	<u>23,094,221</u>
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, diluted	<u>79,566,672</u>	<u>66,556,772</u>
Adjusted net loss per fully exchanged share, diluted	\$ (0.09)	\$ (0.11)

(1) Assumes the exchange of all outstanding Class B common stock, resulting in the inclusion of shares of Class B common stock in the weighted average share count, if not already considered, and the elimination of the noncontrolling interest and recognition of the net income attributable to noncontrolling interests.

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Source: vTv Therapeutics Inc.