



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

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HIGH POINT, N.C., Aug. 04, 2021 (GLOBE NEWSWIRE) -- [vTv Therapeutics Inc.](https://www.vtvtherapeutics.com) (Nasdaq:VTVT) today reported financial results for the second quarter ended June 30, 2021, and provided an update on the progress of its clinical programs.

"We held our first, highly-productive meeting with the FDA following the designation of Breakthrough Therapy for TTP399 as a potential adjunct treatment for type 1 diabetes," said Steve Holcombe, president and CEO, vTv Therapeutics. "Based upon the outcome of this meeting, we are planning to conduct two pivotal studies of TTP399 starting in the first half of 2022. We are appreciative of the ongoing dialogue that the Breakthrough Designation affords us and look forward to continuing to work closely with the agency as we refine the design of these studies in the coming weeks."

Recent Achievements and Outlook

Type 1 Diabetes

- **Breakthrough Therapy Designation Type B Meeting.** 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. The Company held its first Type B meeting with the FDA pursuant to the Breakthrough Therapy designation to discuss the development of TTP399.
- **Mechanistic Study of Ketoacidosis with TTP399.** The Company completed enrollment in the mechanistic study of TTP399 in people with type 1 diabetes. This phase 1 study is designed to assess the impact of TTP399 on ketone body formation, and therefore the risk of diabetic ketoacidosis, during a period of acute insulin withdrawal. vTv expects to report topline results from this mechanistic study in late third quarter or early fourth quarter of 2021.
- **Pivotal Study Planning.** The Company is planning two pivotal, placebo-controlled clinical trials of TTP399 in subjects with type 1 diabetes that are expected to begin in the first half of 2022.

Psoriasis

- **Multiple Ascending Dose Study with HPP737.** The Company completed 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. We expect to report the results from this study in the third quarter.
- **Phase 2 Study Planning.** The Company is planning a phase 2 clinical trial of HPP737 in patients with psoriasis. We are discussing the proposed study design with the FDA during the third quarter and expect to begin the study late in the fourth quarter of 2021 or early in the first quarter of 2022.

License Partner Updates

- **vTv and Cantex Entered into a Strategic Licensing Agreement for Azeliragon.** In June, the Company announced a new strategic collaboration with Cantex Pharmaceuticals under which Cantex will continue the development of azeliragon for the treatment of the complications associated with cancer, including cachexia and pain from bone metastasis. Cantex will be responsible for the development and commercialization of azeliragon and the companies will allocate profits under a tiered arrangement.
- **Reneo Dosed the First Patient in Phase 2b STRIDE Study.** In July, Reneo Pharmaceuticals dosed the first patient in the phase 2b STRIDE Study, designed to assess the efficacy and safety of REN001 for the treatment of patients with primary mitochondrial myopathies.

Funding Updates

- **\$50 Million ATM Program.** The Company added an additional \$50 million of capacity to its at-the-market equity program with Cantor Fitzgerald to fund the ongoing and planned development of TTP399 and HPP737.
- **Registration of Additional Shares to Support Equity Line.** The Company registered an additional 9.4 million shares of Class A Common Stock to provide the continued flexibility to raise capital with share sales to Lincoln Park Capital under the Purchase Agreement entered into in November of 2020.

First Quarter 2021 Financial Results

- **Cash Position:** The Company's cash position as of June 30, 2021, was \$10.8 million compared to \$8.4 million as of March 31, 2021.
- **Revenue:** Revenue for the second quarter of 2021 was an insignificant amount. For the first quarter of 2021 revenue was \$1.0 million. The revenue for the first quarter was non-cash and related to the recognition of revenue pertaining to the Huadong license agreement.
- **R&D Expenses:** Research and development expenses were \$2.4 million and \$3.1 million for the three months ended June 30, 2021 and March 31, 2021, respectively. This decrease of \$0.7 million was driven primarily by the decreases in spending for the Elevage study as the analysis and close out of this study largely occurred in the first quarter as well as a decrease in spending for our study of HPP737 in psoriasis.
- **G&A Expenses:** General and administrative expenses were consistent between periods at \$2.2 million for each of the three months ended June 30, 2021 and March 31, 2021.
- **Other Income/(Expense):** Other income for the three months ended June 30, 2021 was \$3.8 million and was attributable to the changes in the fair value of our investment in Reneo Pharmaceuticals, Inc. which completed its initial public offering in the second quarter of 2021 as well as gains related to a reduction in fair value of the warrants to purchase shares of our own stock issued to a related party (the "Related Party Warrants"). Other expense for the three months ended March 31, 2021 was driven by losses related to an increase in the fair value of the Related Party Warrants.
- **Net Loss Before Non-Controlling Interest:** Net loss before non-controlling interest was \$0.8 million for the second quarter of 2021 compared to net loss of \$5.9 million for the first quarter of 2021.
- **Net Loss Per Share:** Diluted net loss per share was (\$0.01) for the three months ended June 30, 2021 compared to diluted net loss per share of (\$0.08) for the three months ended March 31, 2021, based on weighted-average diluted shares of 58.6 million and 56.5 million for the three-month periods ended June 30, 2021 and March 31, 2021, respectively.

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

	June 30, 2021	March 31, 2021
	(Unaudited)	(Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,835	\$ 8,449
Accounts receivable, net	—	2
Prepaid expenses and other current assets	313	710
Current deposits	124	60
Total current assets	11,272	9,221
Property and equipment, net	322	344
Operating lease right-of-use assets	444	464
Long-term investments	9,622	6,725
Total assets	\$ 21,660	\$ 16,754
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,855	\$ 4,965
Operating lease liabilities	169	162
Current portion of contract liabilities	35	35

Current portion of notes payable	—	—
Total current liabilities	5,059	5,162
Contract liabilities, net of current portion	9	18
Operating lease liabilities, net of current portion	587	633
Warrant liability, related party	3,588	4,519
Other liabilities	50	50
Total liabilities	9,293	10,382
Commitments and contingencies		
Redeemable noncontrolling interest	60,190	62,647
Stockholders' deficit:		
Class A Common Stock	602	576
Class B Common Stock	232	232
Additional paid-in capital	224,457	217,647
Accumulated deficit	(273,114)	(274,730)
Total stockholders' deficit attributable to vTv Therapeutics Inc.	(47,823)	(56,275)
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	\$ 21,660	\$ 16,754

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

	Three Months Ended	
	June 30, 2021	March 31, 2021
Revenue	\$ 9	\$ 987
Operating expenses:		
Research and development	2,437	3,103
General and administrative	2,242	2,164
Total operating expenses	4,679	5,267
Operating loss	(4,670)	(4,280)
Interest income	—	1
Interest expense	—	—
Other income (expense), net	3,829	(1,648)
Loss before income taxes and noncontrolling interest	(841)	(5,927)
Income tax provision	—	15
Net loss before noncontrolling interest	(841)	(5,942)
Less: net loss attributable to noncontrolling interest	(233)	(1,701)
Net loss attributable to vTv Therapeutics Inc.	\$ (608)	\$ (4,241)
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (608)	\$ (4,241)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	\$ (0.01)	\$ (0.08)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	58,615,137	56,472,535

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

	Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Revenue	\$ 9	\$ —	\$ 996	\$ 8
Operating expenses:				
Research and development	2,437	2,509	5,540	6,713
General and administrative	2,242	1,695	4,406	4,145
Total operating expenses	4,679	4,204	9,946	10,858
Operating loss	(4,670)	(4,204)	(8,950)	(10,850)
Interest income	—	—	1	12
Interest expense	—	(222)	—	(390)
Other income (expense), net	3,829	(565)	2,181	(928)

Loss before income taxes and noncontrolling interest	(841)	(4,991)	(6,768)	(12,156)
Income tax provision	—	—	15	—
Net loss before noncontrolling interest	(841)	(4,991)	(6,783)	(12,156)
Less: net loss attributable to noncontrolling interest	(233)	(1,623)	(1,934)	(4,064)
Net loss attributable to vTv Therapeutics Inc.	<u>\$ (608)</u>	<u>\$ (3,368)</u>	<u>\$ (4,849)</u>	<u>\$ (8,092)</u>
Net loss attributable to vTv Therapeutics Inc. common shareholders	<u>\$ (608)</u>	<u>\$ (3,368)</u>	<u>\$ (4,849)</u>	<u>\$ (8,092)</u>
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	<u>\$ (0.01)</u>	<u>\$ (0.07)</u>	<u>\$ (0.08)</u>	<u>\$ (0.18)</u>
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	58,615,137	45,661,221	57,549,755	44,561,886

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, primary mitochondrial myopathy, and pancreatic cancer.

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.

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