



vTv Therapeutics Announces 2021 fourth Quarter and Full Year Financial Results and Provides Corporate Update

03/30/22

HIGH POINT, N.C., March 29, 2022 /PRNewswire/ -- [vTv Therapeutics Inc.](#) (Nasdaq: VTVT) today reported financial results for the fourth quarter and year ended December 31, 2021, and provided an update on the progress of its clinical programs.

"I am dedicated to the long-term growth and development of the Company and look forward to working with vTv's talented employees, scientists, and partners during this exciting time," Mr. Nelson said. "The positive Phase 2 study results and FDA Breakthrough Therapy Designation for *TTP399* are very promising milestones in the development of a novel treatment for type 1 diabetes patients worldwide"

Recent Achievements and Outlook

Corporate

- **Leadership.** On March 1, 2022, the Company appointed Richard Nelson as Acting Chief Executive Officer. Mr. Nelson joined the vTv Board of Directors in 2020, and currently serves as Executive Vice President Corporate & Business Development of Vericast Corp., and Executive Vice President Corporate Development for MacAndrews & Forbes Incorporated. He brings more than 25 years of business and legal experience in mergers & acquisitions and corporate development.

Mr. Nelson will work closely with the Company's Board of Directors as vTv continues to progress in the development of its pipeline of novel therapeutics, particularly *TTP399*, an orally administered treatment for type 1 diabetes.

- **Strategic Focus.** We plan to prioritize the development of our lead program *TTP399*, a novel, oral liver selective glucokinase activator, as a potential treatment for patients with type 1 diabetes ("T1D"), as well as continuing to support our currently partnered programs. Given the strategic focus on these programs, we plan to pause our development activities in the United States on *HPP737* while we evaluate strategic options for it. As part of this planned strategic focus, the Company has reduced its workforce. We are actively seeking to raise non-dilutive capital through licensing *TTP399* in regions outside of North America and Europe and are also actively seeking licensing deals for *HPP737* and other assets. We are currently in active discussions with respect to financing, partnering, and licensing transactions for the further development of *TTP399*.

Type 1 Diabetes

- **Mechanistic Study of Ketoacidosis with *TTP399*.** In October 2021, we announced positive results from the Mechanistic study indicating no increased risk of ketoacidosis with *TTP399* during acute insulin withdrawal in patients with T1D. Patients with type 1 diabetes taking *TTP399* experienced no increase in ketone levels relative to placebo during a period of acute insulin withdrawal, indicating that treatment with *TTP399* presents no increased risk of ketoacidosis. In addition, patients taking *TTP399* had improved fasting plasma glucose levels and experienced fewer hypoglycemic events relative to those taking placebo, consistent and supportive of the previously announced phase 2 Simplici-T1 Study results. Full study results will be published in the Diabetes Obesity and Metabolism journal in conjunction with the 82nd American Diabetes Association Scientific Sessions on June 6th, 2022.
- **Pivotal Study Planning.** The Company is planning two pivotal, placebo-controlled clinical trials of *TTP399* in subjects with type 1 diabetes and has engaged with the Food and Drug Administration (FDA) on the optimal clinical trial designs for these studies. The studies will recruit a total of approximately 1000 patients and at least one of the studies will be one year of treatment. The FDA and the company have agreed on the primary endpoint for the studies as the difference between placebo and *TTP399*-treated group in number of hypoglycemia events. These pivotal studies are expected to start in 3Q

2022.

Fourth Quarter 2021 Financial Results

- **Cash Position:** The Company's cash position as of December 31, 2021, was \$13.4 million compared to \$19.6 million as of September 30, 2021.
- **Revenue:** Revenue for the fourth quarter of 2021 was an insignificant amount. Revenue for the third quarter of 2021 was \$3.0 million, attributable to the satisfaction of milestones under the license agreements with Newsoara Biopharma Co., Ltd. (with respect to *HPP737*) and Reneo Pharmaceuticals, Inc (with respect to *HPP593*).
- **R&D Expenses:** Research and development expenses were \$5.4 million and \$2.4 million in each of the three months ended December 31, 2021, and September 30, 2021, respectively. The changes are attributable to i) increases due to manufacturing and analytical work related to chemistry manufacturing and control "CMC" for pivotal studies, and the startup of *TTP399* toxicology studies in Q4 2021, offset by lower costs in the quarter as the majority of the *TTP399-118* trial was completed earlier in the year, ii) \$2.0 million for a license payment to Novo Nordisk for the completion of *TTP399* phase 2 studies, iii) an increased severance accrual of \$0.6 million, offset by iv) reductions in bonus and share based compensation due to the reduction in workforce in Q4 2021 of \$0.3 million.
- **G&A Expenses:** General and administrative expenses were \$5.7 million and \$2.2 million for each of the three months ended December 31, 2021, and September 30, 2021. The changes are attributable to i) increases in severance expense of \$1.5 million in connection with the Company's restructuring plan that occurred in December 2021, ii) \$0.5 million in stock-based compensation expense due to the modification of awards related to the retirement and separation agreements with several key employees, and iii) increases in legal expense of \$1.2 million.
- **Other Income/(Expense):** Other income for the three months ended December 31, 2021, was \$1.6 million and was driven by changes in the fair value of our investment in Reneo as well as the gains related to a reduction in the fair value of the outstanding warrants to purchase shares of our own stock issued to a related party ("Related Party Warrants"). Other income for the three months ended September 30, 2021, was \$0.2 million and was attributable to the gains related to a reduction in fair value of the Related Party Warrants offset by losses driven by the decrease in the fair value of our investment in Reneo.
- **Net Loss Before Non-Controlling Interest:** Net loss before non-controlling interest was \$9.5 million for the fourth quarter of 2021 compared to net loss before non-controlling interest of \$1.5 million for the third quarter of 2021. The increase in net loss before Non-Controlling Interest was primarily attributable to i) increased severance expense of \$2.1 million, ii) \$2.0 million for a license payment to Novo for the completion of *TTP399* phase 2 studies, iii) an increase in legal expense of \$1.2 million and iv) \$0.5 million in stock-based compensation expense due to the modification of awards related to the retirement and separation agreements with several key employees.
- **Net Loss Per Share:** Diluted net loss per share was (\$0.11) for the three months ended December 31, 2021, compared to diluted net loss per share of (\$0.02) for the three months ended September 30, 2021, based on weighted average diluted shares of 66.8 million and 61.1 million for the three-month periods ended December 31, 2021, and September 30, 2021, respectively.

Full Year 2021 Financial Results

- **Revenue:** Revenues were \$4.0 million and \$6.4 million for the years ended December 31, 2021, and 2020, respectively. The 2021 revenue is attributable to the reallocation of revenue to the license and technology transfer performance obligation made in connection with an amendment to the license agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co. with respect to *TTP273* as well as increases to the transaction prices for the license performance obligations under the Newsoara and Reneo License Agreements due to the satisfaction of development milestones. The 2020 revenue is attributable to the upfront payment and fair value of the equity interest received by the Company in connection with the license agreement with Anteris Bio (with respect to *HPP971*).
- **R&D Expenses:** Research and development expenses were \$13.3 million and \$11.0 million for the years ended December 31, 2021, and 2020, respectively. This increase was attributable to i) spending of \$2.3 million for the development of *HPP737* as we were conducting a Phase 1 multiple ascending dose study for this drug candidate, ii) \$2.0 million for a license payment to Novo for the completion of *TTP399* phase 2 studies, iii) spending of \$1.7 million related to the development of *TTP399* due to the mechanistic study and compound manufacturing, and iv) costs of \$1.6 million for various employee related costs including severance costs related to the Company's restructuring plan, increase in share-based compensation, and reversal of certain performance-based compensation accruals in the prior year due to the

expectation they would not be paid. These increases were offset by a decrease in clinical trial costs of \$5.3 million for *azelliragon* which was mainly driven by discontinuance of its development as a potential treatment of Alzheimer's disease in patients with type 2 diabetes.

- G&A Expenses:** General and administrative expenses were \$12.3 million and \$7.3 million for the years ended December 31, 2021, and 2020, respectively. Such increases were primarily driven by i) severance expense of \$1.5 million in connection with the Company's restructuring plan that occurred in December 2021, ii) \$0.5 million in stock-based compensation expense due to the modification of awards related to the retirement and separation agreements with several key employees and general increase in expense from options issued late 2020, iii) a reversal of certain performance-based compensation accruals in the prior year due to the expectation they would not be paid, and iv) \$1.2 million of additional legal expenses.
- Other Income/(Expense):** Other income/(expense) was \$4.1 million and \$(0.3) million for the years ended December 31, 2021, and 2020, respectively. The increase was driven by an unrealized gain recognized related to the Company's investment in Reneo as well as the gains related to a reduction in fair value of the Related Party Warrants.
- Net Loss Before Non-Controlling Interest:** Net loss before non-controlling interest was \$17.6 million and \$12.8 million for the years ended December 31, 2021, and 2020, respectively. The increase in net loss before Non-Controlling Interest was attributable to i) increased severance expense of \$2.1 million, ii) \$2.0 million for a license payment to Novo for the completion of *TTP399* phase 2 studies, iii) increases in legal expense of \$1.2 million and iv) \$0.5 million in stock-based compensation expense due to the modification of awards related to the retirement and separation agreements with several key employees.
- Net Loss Per Share:** GAAP net loss per share was \$0.21 and \$0.18 for the years ended December 31, 2021, and 2020, respectively, based on weighted average outstanding shares of 60.7 million and 47.1 million for the years ended December 31, 2021, and 2020, respectively. Non-GAAP adjusted net loss per fully exchanged share was \$0.14 and \$0.17 for the years ended December 31, 2021, and 2020, respectively, based on non-GAAP fully exchanged weighted average shares outstanding of 83.8 million and 70.2 million for the years ended December 31, 2021, and 2020, respectively.

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

	December 31, 2021	September 30, 2021
		(Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,415	\$ 19,566
Accounts receivable, net	57	928
Prepaid expenses and other current assets	2,049	1,574
Current deposits	100	103
Total current assets	15,621	22,171
Property and equipment, net	278	300
Operating lease right-of-use assets	402	424
Long-term investments	9,173	8,539
Total assets	\$ 25,474	\$ 31,434
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,023	\$ 4,663
Operating lease liabilities	184	176
Current portion of contract liabilities	35	35
Current portion of notes payable	256	636
Total current liabilities	8,498	5,510
Contract liabilities, net of current portion	—	9
Operating lease liabilities, net of current portion	492	540
Warrant liability, related party	1,262	2,260
Other liabilities	-	50
Total liabilities	10,252	8,369
Commitments and contingencies		
Redeemable noncontrolling interest	24,962	44,610
Stockholders' deficit:		
Class A Common Stock	669	665

Class B Common Stock	232	232
Additional paid-in capital	238,193	236,557
Accumulated deficit	<u>(248,834)</u>	<u>(258,999)</u>
Total stockholders' deficit attributable to vTv Therapeutics Inc.	<u>(9,740)</u>	<u>(21,545)</u>
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	<u>\$ 25,474</u>	<u>\$ 31,434</u>

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

	Three Months Ended	
	December 31, 2021	September 30, 2021
Revenue	\$ 9	\$ 3,000
Operating expenses:		
Research and development	5,402	2,382
General and administrative	5,716	2,221
Total operating expenses	<u>11,118</u>	<u>4,603</u>
Operating income/(loss)	(11,109)	(1,603)
Interest expense	(6)	(6)
Other income (expense), net	1,632	244
Loss before income taxes and noncontrolling interest	(9,483)	(1,365)
Income tax provision	—	100
Net loss before noncontrolling interest	(9,483)	(1,465)
Less: net income/(loss) attributable to noncontrolling interest	(2,432)	(378)
Net income/(loss) attributable to vTv Therapeutics Inc.	<u>\$ (7,051)</u>	<u>\$ (1,087)</u>
Net income/(loss) attributable to vTv Therapeutics Inc. common shareholders	<u>\$ (7,051)</u>	<u>\$ (1,087)</u>
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.02)</u>
Weighted average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	<u>66,785,550</u>	<u>61,073,280</u>

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

	Three Months Ended		For the Year Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
	(Unaudited)			
Revenue	\$ 9	\$ 6,399	\$ 4,005	\$ 6,414
Operating expenses:				
Research and development	5,402	2,534	13,324	11,015
General and administrative	5,716	2,035	12,343	7,251
Total operating expenses	<u>11,118</u>	<u>4,569</u>	<u>25,667</u>	<u>18,266</u>
Operating loss	(11,109)	1,830	(21,662)	(11,852)
Interest income	—	—	1	12
Interest expense	(6)	(67)	(12)	(692)
Other income (expense), net	1,632	(156)	4,057	(270)
Loss before income taxes and noncontrolling interest	(9,483)	1,607	(17,616)	(12,802)
Income tax provision	—	—	115	—
Net loss before noncontrolling interest	(9,483)	1,607	(17,731)	(12,802)
Less: net loss attributable to noncontrolling interest	(2,432)	481	(4,744)	(4,303)
Net loss attributable to vTv Therapeutics Inc.	<u>\$ (7,051)</u>	<u>\$ 1,126</u>	<u>\$ (12,987)</u>	<u>\$ (8,499)</u>
Net loss attributable to vTv Therapeutics Inc. common shareholders	<u>\$ (7,051)</u>	<u>\$ 1,126</u>	<u>\$ (12,987)</u>	<u>\$ (8,765)</u>
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	<u>\$ (0.11)</u>	<u>\$ 0.02</u>	<u>\$ (0.21)</u>	<u>\$ (0.18)</u>
Weighted average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	<u>66,785,550</u>	<u>74,397,085</u>	<u>60,732,636</u>	<u>47,137,917</u>

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. 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. In addition, we may not be able to successfully complete a successful financing, partnering or licensing transactions with respect to TTP399. 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	
	December 31, 2021	September 30, 2021
Numerator:		
Net income/(loss) attributable to vTv Therapeutics Inc. common shareholders	\$ (7,051)	\$ (1,087)
Other income/(expense) - related party	998	(1,328)
Share-based compensation expense	994	474
Unrealized gain on investments	634	(1,814)
Reallocation of net income attributable to noncontrolling interest from the assumed exchange of Class B shares ⁽¹⁾	(2,432)	(378)
Adjusted net income/(loss) before noncontrolling interest	<u>\$ (6,857)</u>	<u>\$ (4,133)</u>
Denominator:		
Weighted average number of vTv Therapeutics Inc. Class A Common Stock, diluted	66,785,550	61,073,280
Assumed exchange of Class B Common Stock ⁽¹⁾	23,093,860	23,093,860
Adjusted proforma fully exchanged weighted average shares of Class A common stock outstanding, diluted	<u>89,879,410</u>	<u>84,167,140</u>
Adjusted net loss per fully exchanged share, diluted	<u>\$ (0.08)</u>	<u>\$ (0.05)</u>

	Three Months Ended		Twelve Months Ended	
	December 31, 2021	2020	December 31, 2021	2020
Numerator:				
Net income/(loss) attributable to vTv Therapeutics Inc. common shareholders	\$ (7,051)	\$ 1,126	\$ (12,987)	\$ (8,499)
Other income/(expense) - related party	998	(156)	1,609	(270)
Share-based compensation expense	994	272	2,356	1,009
Unrealized gain on investments	634	—	2,448	—
Reallocation of net income attributable to noncontrolling interest from the assumed exchange of Class B shares ⁽¹⁾	(2,432)	481	(4,744)	(4,303)
Adjusted net income/(loss) before noncontrolling interest	<u>\$ (6,857)</u>	<u>\$ 1,723</u>	<u>\$ (11,318)</u>	<u>\$ (12,063)</u>
Denominator:				

Weighted average number of vTv Therapeutics Inc. Class A Common Stock, diluted	66,785,550	74,397,085	60,732,636	47,137,917
Assumed exchange of Class B Common Stock ⁽¹⁾	<u>23,093,860</u>	<u>—</u>	<u>23,093,860</u>	<u>23,094,221</u>
Adjusted proforma fully exchanged weighted average shares of Class A common stock outstanding, diluted	<u>89,879,410</u>	<u>74,397,085</u>	<u>83,826,496</u>	<u>70,232,138</u>
Adjusted net income/(loss) per fully exchanged share, diluted	<u>\$ (0.08)</u>	<u>\$ 0.02</u>	<u>\$ (0.14)</u>	<u>\$ (0.17)</u>

(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.

Contacts

Investors:

IR@vtvtherapeutics.com.

or

Media:

PR@vtvtherapeutics.com

 View original content: <https://www.prnewswire.com/news-releases/vtv-therapeutics-announces-2021-fourth-quarter-and-full-year-financial-results-and-provides-corporate-update-301513417.html>

SOURCE vTv Therapeutics Inc.