



vTv Therapeutics Announces 2020 Third Quarter Financial Results and Update

November 5, 2020

HIGH POINT, N.C., Nov. 05, 2020 (GLOBE NEWSWIRE) -- [vTv Therapeutics Inc.](https://www.vtvtherapeutics.com) (Nasdaq:VTVT) today reported financial results for the third quarter ended September 30, 2020, and provided an update on the progress of its clinical programs.

“Following our decision to conclude enrollment in the Elevage Study at the end of September, we look forward to announcing topline results from this phase 2 study of *azeliragon* in December,” said Steve Holcombe, president and CEO. “In addition, we are planning a mechanistic study of TTP399 to start early in the new year to better understand its impact on diabetic ketoacidosis. Finally, we are planning a phase 1 study of our PDE4 inhibitor compound, HPP737, as an initial step towards a proof-of-concept study in psoriasis. We expect to report topline results from both the mechanistic study of TTP399 and the phase 1 study of HPP737 during the second quarter of 2021.”

Recent Achievements and Outlook

Type 1 Diabetes

- **FDA Engagement and Pivotal Study Planning.** vTv continued its dialogue with the FDA during the third quarter surrounding the design and endpoints of its planned pivotal studies of TTP399 as an adjunct to insulin therapy for type 1 diabetes. Based upon the FDA's feedback, the Company plans to conduct a placebo-controlled six-month clinical trial in approximately 400 subjects, followed by a second placebo-controlled six-month clinical trial to be initiated nine to twelve months after initiation of the first pivotal trial. The FDA also confirmed that the effect size of TTP399 on events of hypoglycemia as demonstrated in the Phase 2 SimpliciT-1 Study are clinically meaningful and that a reduction in events of hypoglycemia would be an acceptable clinical endpoint for evaluation of a therapy for the treatment of type 1 diabetes.
- **Development of Mechanistic Study of Ketoacidosis.** To further support the hypothesis that TTP399 may help reduce the incidence of ketoacidosis, vTv plans to conduct a mechanistic study in a small number of patients with type 1 diabetes to determine the impact of TTP399 on ketone body formation during a period of acute insulin withdrawal. The Company proposed the mechanistic study to the FDA, and the FDA recommended that the study be performed in support of the planned pivotal trials. vTv expects the mechanistic study to be initiated in the first quarter of 2021 and to report topline results in the second quarter of 2021.
- **Two Oral Presentations at EASD of SimpliciT-1 Study Results.** Members of vTv's TTP399 clinical development team, including Chief Scientific Officer Dr. Carmen Valcarce, presented additional data at the 56th Annual European Association for the Study of Diabetes on the effects of TTP399 on hypoglycemia and ketone body formation from the positive SimpliciT-1 Study.

Dementia with Diabetes

- **Enrollment concluded for Phase 2 Elevage Study of azeliragon.** On September 30, vTv concluded enrollment of patients in the Elevage Study. Forty-three (43) patients with mild probable Alzheimer's disease and type 2 diabetes were enrolled in the study. The study is designed to evaluate the effect of six-months of treatment with azeliragon on cognitive performance. The Company plans to report top-line results for substantially all of the enrolled patients during December 2020, earlier than previously expected. The objective of the Elevage Study is to replicate in a randomized double-blind, placebo controlled study the results observed in a post hoc analysis of the phase 3 STEADFAST trial A-Study in which a subgroup of forty-seven (47) patients with mild Alzheimer's disease and type 2 diabetes treated with azeliragon demonstrated nominally statistically significant improvements in cognition on the ADAS-cog11 scale of 5.5 points ($p=0.006$) at month 18 compared to the same subgroup of patients treated with placebo. Azeliragon associated improvement was nominally significant as early as month 6 on the ADAS-cog11 scale (4.9 points, $p<0.001$).
- **Elevage Study Update to be Presented at CTAD.** Dr. Ann Gooch presented an update on the Elevage Study focusing on the demographic and baseline characteristics data of enrolled subjects at the 13th Clinical Trials on Alzheimer's Disease conference on November 4, 2020.

Psoriasis

- **Multiple Ascending Dose Study with HPP737.** The Company is planning a phase 1 multiple ascending dose study to assess the safety, tolerability, and pharmacokinetic profile of HPP737, a PDE4 inhibitor, in healthy volunteers. vTv expects to initiate the study in the first quarter of 2021 and to report topline results in the second quarter of 2021.

Third Quarter 2020 Financial Results

- **Cash Position:** The Company's cash position as of September 30, 2020, was \$1.8 million compared to \$6.4 million as of June 30, 2020.
- **Revenue:** Revenues were insignificant for both the second and third quarters of 2020.
- **R&D Expenses:** Research and development expenses were \$1.8 million and \$2.5 million for the three months ended September 30, 2020 and June 30, 2020, respectively. This decrease of \$0.7 million was driven primarily by the reversal of certain performance-based compensation accruals that are no longer expected to be paid.
- **G&A Expenses:** General and administrative expenses were \$1.1 million for the third quarter of 2020 and \$1.7 million for the second quarter, respectively. The decrease of \$0.6 million was driven by the reversal of certain performance-based compensation accruals that are no longer expected to be paid.
- **Net Loss Before Non-Controlling Interest:** Net loss before non-controlling interest was \$2.3 million for the third quarter of 2020 compared to \$5.0 million for the second quarter of 2020.
- **Net Loss Per Share:** GAAP net loss per share was \$0.03 and \$0.07 for the three months ended September 30, 2020 and June 30, 2020, respectively, based on weighted-average shares of 48.2 million and 45.7 million for the three-month periods ended September 30, 2020 and June 30, 2020, respectively. Non-GAAP net loss per fully exchanged share was \$0.02 and \$0.08 for the three months ended September 30, 2020 and June 30, 2020, respectively, based on non-GAAP fully exchanged weighted-average shares of 71.3 million and 68.8 million for the three months ended September 30, 2020 and June 30, 2020, respectively.

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

	<u>September 30,</u> <u>2020</u>	<u>June 30</u> <u>2020</u>
	(Unaudited)	(Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,827	\$ 6,392
Accounts receivable, net	14	—
Prepaid expenses and other current assets	1,306	299
Current deposits	531	87
Total current assets	<u>3,678</u>	<u>6,778</u>
Property and equipment, net	389	412
Operating lease right-of-use assets	499	514
Long-term investments	2,480	2,480
Long-term deposits	—	444
Total assets	<u>\$ 7,046</u>	<u>\$ 10,628</u>
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,747	\$ 6,697
Operating lease liabilities	149	143
Current portion of contract liabilities	31	31
Current portion of notes payable	2,369	4,543
Total current liabilities	<u>8,296</u>	<u>11,414</u>
Contract liabilities, net of current portion	1,017	1,025
Operating lease liabilities, net of current portion	717	756
Warrant liability, related party	2,715	3,529
Other liabilities	82	54
Total liabilities	<u>12,827</u>	<u>16,778</u>
Commitments and contingencies		
Redeemable noncontrolling interest	45,591	63,378
Stockholders' deficit:		
Class A Common Stock	492	479
Class B Common Stock	232	232

Additional paid-in capital	201,243	198,634
Accumulated deficit	(253,339)	(268,873)
Total stockholders' deficit attributable to vTv Therapeutics Inc.	(51,372)	(69,528)
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	\$ 7,046	\$ 10,628

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

	Three Months Ended	
	September 30, 2020	June 30, 2020
Revenue	\$ 7	\$ —
Operating expenses:		
Research and development	1,768	2,509
General and administrative	1,071	1,695
Total operating expenses	2,839	4,204
Operating loss	(2,832)	(4,204)
Interest expense	(235)	(222)
Other income (expense), net	814	(565)
Loss before income taxes and noncontrolling interest	(2,253)	(4,991)
Income tax provision	—	—
Net loss before noncontrolling interest	(2,253)	(4,991)
Less: net loss attributable to noncontrolling interest	(720)	(1,623)
Net loss attributable to vTv Therapeutics Inc.	\$ (1,533)	\$ (3,368)
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (1,533)	\$ (3,368)
Net loss per share of vTv Therapeutics Inc. Class A		
Common Stock, basic and diluted	\$ (0.03)	\$ (0.07)
Weighted-average number of vTv Therapeutics Inc.		
Class A Common Stock, basic and diluted	48,238,285	45,661,221

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

	Three Months Ended		For the Nine Months Ended	
	September 30, 2020	2019	September 30, 2020	2019
	(Unaudited)		(Unaudited)	
Revenue	\$ 7	\$ 8	\$ 15	\$ 2,757
Operating expenses:				
Research and development	1,768	3,663	8,481	10,713
General and administrative	1,071	1,770	5,216	6,548
Total operating expenses	2,839	5,433	13,697	17,261
Operating loss	(2,832)	(5,425)	(13,682)	(14,504)
Interest income	—	15	12	41
Interest expense	(235)	(404)	(625)	(1,544)
Other income (expense), net	814	(146)	(114)	1,051
Loss before income taxes and noncontrolling interest	(2,253)	(5,960)	(14,409)	(14,956)
Income tax provision	—	—	—	100
Net loss before noncontrolling interest	(2,253)	(5,960)	(14,409)	(15,056)
Less: net loss attributable to noncontrolling interest	(720)	(2,352)	(4,784)	(6,411)
Net loss attributable to vTv Therapeutics Inc.	\$ (1,533)	\$ (3,608)	\$ (9,625)	\$ (8,645)

Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (1,533)	\$ (3,608)	\$ (9,625)	\$ (12,880)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	\$ (0.03)	\$ (0.13)	\$ (0.21)	\$ (0.46)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	48,238,285	32,126,130	45,796,298	27,709,486

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, Alzheimer's disease, and psoriasis. vTv's development partners are pursuing additional indications in type 2 diabetes, chronic obstructive pulmonary disease (COPD), and genetic mitochondrial diseases.

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 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	
	September 30, 2020	June 30, 2020
Numerator:		
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (1,533)	\$ (3,368)
Other income - related party	814	(565)
Share-based compensation expense	171	186
Deemed distribution to related party	—	—
Reallocation of net income attributable to noncontrolling interest from the assumed exchange of Class B shares ⁽¹⁾	(720)	(1,623)
Adjusted net loss before noncontrolling interest	\$ (1,268)	\$ (5,370)
Denominator:		
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	48,238,285	45,661,221

Assumed exchange of Class B Common Stock ⁽¹⁾	23,094,221	23,094,221
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	71,332,506	68,755,442
Adjusted net loss per fully exchanged share, basic and diluted	\$ (0.02)	\$ (0.08)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (1,533)	\$ (4,115)	\$ (9,625)	\$ (12,880)
Other income - related party	814	(146)	(114)	1,050
Share-based compensation expense	171	413	737	1,095
Deemed distribution to related party	—	507	—	4,235
Reallocation of net income attributable to noncontrolling interest from the assumed exchange of Class B shares ⁽¹⁾	(720)	(2,352)	(4,784)	(6,411)
Adjusted net loss before noncontrolling interest	\$ (1,268)	\$ (5,693)	\$ (13,786)	\$ (12,911)
Denominator:				
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	48,238,285	32,126,130	45,796,298	27,709,486
Assumed exchange of Class B Common Stock ⁽¹⁾	23,094,221	23,094,221	23,094,221	23,094,221
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	71,332,506	55,220,351	68,890,519	50,803,707
Adjusted net loss per fully exchanged share, basic and diluted	\$ (0.02)	\$ (0.10)	\$ (0.20)	\$ (0.25)

(1) Assumes the exchange of all outstanding Class B common stock, resulting in the elimination of the noncontrolling interest and recognition of the net income attributable to noncontrolling interests.

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Source: vTv Therapeutics Inc.