



vTv Therapeutics Announces 2019 Third Quarter Financial Results and Update

10/30/19

Simplici-T-1 Study of TTP399 in patients with type 1 diabetes fully-enrolled

Elevage Study of azeliragon in patients with mild Alzheimer's disease with type 2 diabetes actively enrolling

HIGH POINT, N.C., Oct. 30, 2019 (GLOBE NEWSWIRE) -- [vTv Therapeutics Inc.](http://www.vtvtherapeutics.com) (Nasdaq:VTVT) today reported financial results for the third quarter that ended September 30, 2019, and provided an update on recent achievements, events, and its ongoing clinical trials in type 1 diabetes and Alzheimer's disease.

"We hosted an informative type 1 diabetes key opinion leader event with JDRF this quarter where two prominent KOLs, Drs. John Buse and Kevan Herold, shared important information including that, despite the increasingly widespread use of improved technologies like continuous glucose monitoring, nearly 80% of individuals with type 1 diabetes fail to achieve the American Diabetes Association's target goals for HbA1c," said Steve Holcombe, chief executive officer, vTv Therapeutics. "Based on the data we've seen to date in our trial of TTP399 in patients with type 1 diabetes, we believe our glucokinase activator could eventually provide a meaningful treatment option to patients with type 1 diabetes that would lower A1c, improve glycemic control and reduce daily insulin use, without increasing hypoglycemic events."

"We are also pleased that we are continuing to make progress with the Elevage Study of azeliragon in patients with mild Alzheimer's disease with type 2 diabetes that is expected to read-out in late 2020 or early 2021."

Recent Achievements and Outlook

Type 1 Diabetes Study

- **Completed enrollment for Part 2 of the Simplici-T₁ Study.** In September 2019, we completed enrollment of patients in part 2 of the phase 2 Simplici-T₁ Study, a 12-week study to evaluate TTP399 as an adjunct to insulin therapy for patients with type 1 diabetes. We expect to report results in the latter part of the first quarter of 2020.
- **Presented Additional Positive Data from Part 1 of the Simplici-T₁ Study.** In September 2019, we presented positive continuous glucose monitor (CGM) and insulin dose data from the patients with complete CGM profiles from part 1 of the Simplici-T₁ Study at the 55th Annual Meeting of the European Association for the Study of Diabetes. In addition to the previously presented topline improvement in HbA1c of 0.7% relative to placebo, key results from this presentation included:
 - Patients taking TTP399 treatment (n=6) had increased "Time in Range" from baseline to end of treatment by 11% (2.7 hours) (p=0.055) per day (24 hours), and by 12% (1.7 hours) (p=0.04) during the critical waking hours (7am-9pm) relative to placebo (n=9).
 - Patients taking TTP399 treatment reduced the total daily mealtime bolus insulin dose by 23% compared to 4% for placebo while significantly improving glycemic control.
 - Patients in the TTP399 treatment group experienced fewer Level 1 (≥ 54 -70 mg/dl) and Level 2 (< 54 mg/dl) hypoglycemic events than patients in the placebo group.

Alzheimer's Disease Study

- **Enrollment continues for Phase 2/3 Elevage Study of azeliragon.** We began enrolling patients in the phase 2 part of the Elevage Study to evaluate the efficacy and safety of azeliragon in patients with mild Alzheimer's disease (AD) and type 2 diabetes.

The Elevage Study is designed to confirm the positive post-hoc subgroup results from the previous phase 3 study of azeliragon in patients with mild Alzheimer's disease in which the subgroup of AD patients with type 2 diabetes (defined by

an HbA1c of greater than 6.5% at any time in the study) treated with azeliragon demonstrated a potential benefit in both cognition and function relative to those treated with placebo.

The phase 2 part of the Elevage Study will evaluate the efficacy and safety of azeliragon in patients with mild Alzheimer's disease (screening MMSE 21 to 26, baseline MMSE 19 to 27; and ADAS-cog14 score ≥ 10) and type 2 diabetes (screening HbA1c 6.5% to 9.5%, inclusive). We expect to report topline results from the phase 2 proof of concept study by late 2020 or early 2021.

Recent Events

- **Hosted Key Opinion Leader (KOL) Event to Discuss the Type 1 Diabetes Landscape and Emerging Therapies as Adjuncts to Insulin.** In October, vTv hosted a KOL event to provide an opportunity to learn more about type 1 diabetes. Dr. John Buse, UNC-CH; Dr. Kevan Herold, Yale University; Dr. Esther Latres, JDRF International; and Dr. Carmen Valcarce, vTv Therapeutics, presented to a diverse audience of analysts, investors, and members of the type 1 diabetes community. The KOLs reported that patients with type 1 diabetes have a serious, unmet need for an adjunct to insulin treatment.

An archived version of the event can be found [here](#).

Second Quarter 2019 Financial Results

- **Cash Position:** Cash and cash equivalents as of September 30, 2019, were \$2.4 million compared to \$1.5 million as of June 30, 2019.
- **Revenue:** Revenues were not material for the third quarter of 2019 versus \$1.8 million in the second quarter of 2019. Revenue recognized in the second quarter of 2019 was due to a milestone recognized under our license agreement with Newsoara and the continued amortization of revenue from our license agreement with Reneo over the transfer services period.
- **R&D Expenses:** Research and development expenses were \$3.7 million in the third quarter of 2019 and \$4.2 million in the second quarter of 2019. The decrease in these costs was driven primarily by the decreases in costs for the Elevage Study. Such costs were higher in the second quarter of 2019 as we were performing startup activities related to the sites and initiation of patient enrollment.
- **G&A Expenses:** General and administrative expenses were \$1.8 million and \$2.4 million in each of the third and second quarters of 2019, respectively. The decrease in these costs is related to the recognition of a gain on the sale of laboratory equipment in the third quarter of 2019 as well as overall lower spending in the quarter.
- **Net Loss Before Non-Controlling Interest:** Net loss before non-controlling interest was \$6.0 million for the third quarter of 2019 compared to net loss before non-controlling interest of \$5.1 million for the second quarter of 2019.
- **Net Loss Per Share:** GAAP net loss per share was \$0.13 and \$0.10 for the three months ended September 30, 2019 and June 30, 2019, respectively, based on weighted-average shares of 32.1 million and 28.0 million for the three month periods ended September 30, 2019 and June 30, 2019, respectively. Non-GAAP net loss per fully exchanged share was \$0.10 and \$0.09 for the three months ended September 30, 2019 and June 30, 2019, respectively, based on non-GAAP fully exchanged weighted-average shares of 55.2 million and 51.1 million for the three months ended September 30, 2019 and June 30, 2019, respectively.

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

	September 30, 2019 (Unaudited)	June 30 2019 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,436	\$ 1,462
Accounts receivable, net	10	1,822
Prepaid expenses and other current assets	870	145
Current deposits	251	367

Total current assets	3,567	3,796
Restricted cash and cash equivalents, long-term	2,500	2,500
Property and equipment, net	46	54
Operating lease right-of-use assets	85	167
Long-term investments	2,480	2,480
Long-term deposits	444	75
Total assets	\$ 9,122	\$ 9,072
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,898	\$ 8,326
Operating lease liabilities	91	178
Current portion of deferred revenue	31	27
Current portion of notes payable	7,442	8,646
Total current liabilities	14,462	17,177
Notes payable, net of current portion	1,363	2,185
Deferred revenue, net of current portion	1,040	1,052
Warrant liability, related party	1,878	1,240
Other liabilities	260	260
Total liabilities	19,003	21,914
Commitments and contingencies		
Redeemable noncontrolling interest	37,268	37,060
Stockholders' deficit:		
Class A Common Stock	354	298
Class B Common Stock	232	232
Additional paid-in capital	175,990	167,125
Accumulated deficit	(223,725)	(217,557)
Total stockholders' deficit attributable to vTv Therapeutics Inc.	(47,149)	(49,902)
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	\$ 9,122	\$ 9,072

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

	Three Months Ended	
	September 30, 2019	June 30, 2019
Revenue	\$ 8	\$ 1,828
Operating expenses:		
Research and development	3,663	4,228
General and administrative	1,770	2,392
Total operating expenses	5,433	6,620
Operating loss	(5,425)	(4,792)
Interest income	15	16
Interest expense	(404)	(514)
Other (expense) income, net	(146)	276
Loss before income taxes and noncontrolling interest	(5,960)	(5,014)
Income tax provision	—	100
Net loss before noncontrolling interest	(5,960)	(5,114)
Less: net loss attributable to noncontrolling interest	(2,352)	(2,232)
Net loss attributable to vTv Therapeutics Inc.	\$ (3,608)	\$ (2,882)
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (4,115)	\$ (2,882)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	\$ (0.13)	\$ (0.10)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	32,126,130	28,037,628

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

Three Months Ended September 30,

For the Nine Months Ended
September 30,

	2019	2018	2019	2018
Revenue	\$ 8	\$ 3,375	\$ 2,757	\$ 7,912
Operating expenses:				
Research and development	3,663	2,698	10,713	20,235
General and administrative	1,770	2,158	6,548	7,150
Total operating expenses	5,433	4,856	17,261	27,385
Operating loss	(5,425)	(1,481)	(14,504)	(19,473)
Interest income	15	13	41	47
Interest expense	(404)	(822)	(1,544)	(2,547)
Other (expense) income, net	(146)	329	1,051	656
Loss before income taxes and noncontrolling interest	(5,960)	(1,961)	(14,956)	(21,317)
Income tax provision	—	—	100	200
Net loss before noncontrolling interest	(5,960)	(1,961)	(15,056)	(21,517)
Less: net loss attributable to noncontrolling interest	(2,352)	(1,165)	(6,411)	(14,697)
Net loss attributable to vTv Therapeutics Inc.	\$ (3,608)	\$ (796)	\$ (8,645)	\$ (6,820)
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (4,115)	\$ (796)	\$ (12,880)	\$ (6,820)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	\$ (0.13)	\$ (0.06)	\$ (0.46)	\$ (0.64)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	32,126,130	12,305,949	27,709,486	10,701,599

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 inflammatory disorders. 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, 2019	June 30, 2019
Numerator:		
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (4,115)	\$ (2,882)
Other income - related party	(146)	275
Share-based compensation expense	413	401
Deemed distribution to related party	507	—

Reallocation of net income attributable to noncontrolling interest from the assumed exchange of Class B shares ⁽¹⁾	(2,352)	(2,232)
Adjusted net loss before noncontrolling interest	\$ (5,693)	\$ (4,438)
Denominator:				
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	32,126,130		28,037,628	
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	55,220,351		51,131,849	
Adjusted net loss per fully exchanged share, basic and diluted	\$ (0.10)	\$ (0.09)

	Three Months Ended September 30,		Nine Months Ended September 30,					
	2019	2018	2019	2018				
Numerator:								
Net loss attributable to vTv Therapeutics Inc. common shareholders	\$ (4,115)	\$ (796)	\$ (12,880)	\$ (6,820)
Other income - related party	(146)	319		1,050		610	
Share-based compensation expense	413		579		1,095		2,345	
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⁾	(2,352)	(1,165)	(6,411)	(14,697)
Adjusted net loss before noncontrolling interest	\$ (5,693)	\$ (1,063)	\$ (12,911)	\$ (18,562)
Denominator:								
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	32,126,130		12,305,949		27,709,486		10,701,599	
Assumed exchange of Class B Common Stock ⁽¹⁾	23,094,221		23,114,652		23,094,221		23,101,279	
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	55,220,351		35,420,601		50,803,707		33,802,878	
Adjusted net loss per fully exchanged share, basic and diluted	\$ (0.10)	\$ (0.03)	\$ (0.25)	\$ (0.55)

(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.

Contacts

Investors:

vTv Therapeutics Inc.

IR@vtvtherapeutics.com

or

Media:

Josh Vlasto, 212-572-5969

PR@vtvtherapeutics.com



Source: vTv Therapeutics Inc.