vTv Therapeutics Reports 2018 First Quarter Financial and Operational Results and Recent Highlights

05/15/18

HIGH POINT, N.C.--(BUSINESS WIRE)--May 15, 2018-- vTv Therapeutics Inc. (Nasdaq:VTVT) today reported financial and operational results for the first quarter that ended March 31, 2018.

“We continue to make progress on all of our major programs,” said Steve Holcombe, chief executive officer, vTv Therapeutics. “While our initial readout of the results of our STEADFAST Part A Study was not what we had hoped for, we are pleased with the results of our subgroup analysis and are continuing our work in preparation for the Part B readout with a new prospectively-defined target population. We also are continuing to move our diabetes compounds into Phase 2 studies. Our GKA activator is now enrolling patients in a Phase 2 trial for type 1 diabetes and we expect interim results by year-end. We also continue to work with Huadong Medicine in China on the commencement of a Phase 2b study for our GLP-1r compound to test lower dosing levels. We remain enthusiastic for the success of these programs.”

Pre-specifying New Subgroup with the FDA for Part B Readout Expected in June

Last week, the company announced that, based on post hoc analyses of the data from Part A of the company’s Phase 3 STEADFAST study of the investigational medication azeliragon in people with mild Alzheimer’s disease, despite not meeting co-primary endpoints, it had identified a subpopulation that showed statistically significant benefit (unadjusted for multiple post hoc comparisons) from azeliragon relative to placebo on ADAS-cog. The identified subpopulation consisted of participants with peak azeliragon blood plasma concentration of less than 7.5 ng/mL.

Based on the subpopulation data analyses from the Part A Study and the prior azeliragon trials, the company will submit a revised Statistical Analysis Plan (SAP) to the Food and Drug Administration for the Part B Study that pre-specifies a target population for the primary study analysis and expects to report Part B topline efficacy results based on 12 month data in June 2018.

The patients in the identified subgroup (n=~48) had a -1.9 point improvement in ADAS-cog relative to the placebo group (n=200) which was statistically significant (unadjusted for multiple post hoc comparisons) ($p = 0.02$), and a 0.5 point improvement on CDR-sb relative to placebo ($p = .06$) despite the smaller sample size.

First Quarter 2018 Financial Results

- **Cash Position**: Cash and cash equivalents as of March 31, 2018, were $6.5 million compared to $11.8 million as of December 31, 2017.
- **R&D Expenses**: Research and development expenses were $8.9 million in the first quarter of 2018, compared to $10.1 million in the fourth quarter of 2017. The decrease in research and development expenses were primarily driven by decreased costs related to certain azeliragon preclinical studies which were completed in the fourth quarter of 2017. Additionally, research and development expenses related to compound manufacturing costs for azeliragon as well as the STEADFAST and OLE studies were lower during the first quarter of 2018.
- **G&A Expenses**: General and administrative expenses were $2.3 million and $2.9 million, for the first quarter of 2018 and the fourth quarter of 2017, respectively. The decrease in general and administrative cost was primarily due to lower incentive compensation costs in the first quarter of 2018 as well as lower expenses related to professional services. The cost of professional services were higher in the fourth quarter of 2017 due to the license transactions that were entered into in December 2017.
- **Net Loss Before Non-Controlling Interest**: Net loss before non-controlling interest was $10.0 million for the first quarter of 2018 compared to net loss before non-controlling interest of $14.6 million for the fourth quarter of 2017.
- **Net Loss per Share**: GAAP net loss per share was $0.30 and $0.44 for the three months ended March 31, 2018 and December 31, 2017, respectively, based on weighted-average shares of 9.7 million in each period. Non-GAAP net loss per fully exchanged share was $0.30 and $0.44 for the three months ended March 31, 2018 and December 31, 2017, respectively, based on non-GAAP fully exchanged weighted-average shares of 32.8 million in each period.

Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 6,535	$ 11,758
Restricted cash and cash equivalents	—	162
Accounts receivable, net	210	8,000
Prepaid expenses and other current assets	471	442
Current deposits	2,256	—
Total current assets	9,472	20,362
Restricted cash and cash equivalents, long-term	2,500	2,500
Property and equipment, net	241	283
Long-term investments	2,480	2,480
Long-term deposits	36	2,292
Total assets	$ 14,729	$ 27,917
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 11,296	$ 13,901
Current portion of deferred revenue	8,754	8,757
Current portion of notes payable	6,771	4,271
Total current liabilities	26,821	26,929
Notes payable	13,091	15,316
Deferred revenue, net of current portion	2,436	4,497
Warrant liability, related party	517	492
Other liabilities	255	290
Total liabilities	43,120	47,524
Commitments and contingencies		
Redeemable noncontrolling interest	120,397	131,440
Stockholders' deficit:		
Class A Common Stock	97	97
Class B Common Stock	232	232
Additional paid-in capital	128,796	127,682
Accumulated deficit	(277,913)	(279,058)
Total stockholders' deficit attributable to vTv Therapeutics Inc.	(148,788)	(151,047)
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	$ 14,729	$ 27,917

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

	Three Months Ended	
	March 31, 2018	December 31, 2017
Revenue	$ 2,064	$ 233
Operating expenses:		
Research and development	8,943	10,068
General and administrative	2,255	2,937
Total operating expenses	11,198	13,005
Operating loss	(9,134)	(12,772)
Interest income	18	22
Interest expense	(855)	(852)
Other income (expense), net	11	(190)
Loss before income taxes and noncontrolling interest	(9,960)	(13,792)
Income tax provision	—	800
Net loss before noncontrolling interest	(9,960)	(14,592)
Less: net loss attributable to noncontrolling interest	(7,008)	(10,281)
Net loss attributable to vTv Therapeutics Inc.	$ (2,952)	$ (4,311)

Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	$ (0.30)	$ (0.44)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	9,699,721	9,693,254

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

	Three Months Ended March 31,	
	2018	**2017**
Revenue	$ 2,064	$ 30
Operating expenses:		
Research and development	8,943	10,960
General and administrative	2,255	2,824
Total operating expenses	11,198	13,784
Operating loss	(9,134)	(13,754)
Interest income	18	27
Interest expense	(855)	(559)
Other income (expense), net	11	—
Loss before income taxes and noncontrolling interest	(9,960)	(14,286)
Income tax provision	—	—
Net loss before noncontrolling interest	(9,960)	(14,286)
Less: net loss attributable to noncontrolling interest	(7,008)	(10,066)
Net loss attributable to vTv Therapeutics Inc.	$ (2,952)	$ (4,220)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	$ (0.30)	$ (0.44)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	9,699,721	9,693,254

About vTv Therapeutics

vTv Therapeutics Inc. is a clinical-stage biopharmaceutical company engaged in the discovery and development of orally administered small molecule drug candidates to fill significant unmet medical needs. vTv has a pipeline of clinical drug candidates led by programs for the treatment of Alzheimer's disease and diabetes as well as treatment of inflammatory disorders.

About STEADFAST

The STEADFAST study, two independent and identical randomized, double-blind, placebo-controlled Phase 3 trials (Part A and Part B), was designed to investigate the safety and efficacy of azeliragon as a potential treatment for patients with mild Alzheimer's disease. The 18-month study targeted enrollment of 800 patients (400 in each trial). The first trial enrolled patients in the United States and Canada who had a clinical diagnosis of mild Alzheimer's disease and an MRI consistent with this diagnosis. Enrollment of the second trial included study sites in the United Kingdom, Ireland, Australia, New Zealand and South Africa. Clinical trials involving azeliragon, including the Part B Study and the open-label extension study have been terminated based on the topline results from the Part A Study showing the trial failed to meet either of the co-primary endpoints. Topline efficacy results from the Part B Study are expected to be announced in June of 2018.

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 earnings per fully exchanged share, which is a non-GAAP financial measure. Non-GAAP earnings per fully exchanged share is defined as net loss attributable to vTv Therapeutics Inc. including the loss attributable to the non-controlling interest and assuming 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. 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 earnings per fully exchanged share, basic and diluted to its most directly comparable GAAP measure, net loss per share of vTv Therapeutics Class A common stock, basic and diluted and the computation of the components of this non-GAAP measure:

	Three Months Ended	
	March 31, 2018	**December 31, 2017**
Numerator:		
Net loss attributable to vTv Therapeutics Inc.	$ (2,952)	$ (4,311)
Reallocation of net income attributable to non-controlling interest from the assumed exchange of Class B shares [1]	(7,008)	(10,281)
Net loss before noncontrolling interest	$ (9,960)	$ (14,592)
Denominator:		
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	9,699,721	9,693,254
Assumed exchange of Class B Common Stock [1]	23,115,631	23,119,246
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	32,815,352	32,812,500
Adjusted proforma earnings per fully exchanged share, basic and diluted	$ (0.30)	$ (0.44)

	Three Months Ended March 31,	
	2018	**2017**
Numerator:		
Net loss attributable to vTv Therapeutics Inc.	$ (2,952)	$ (4,220)
Reallocation of net income attributable to non-controlling interest from the assumed exchange of Class B shares [1]	(7,008)	(10,066)
Net loss before noncontrolling interest	$ (9,960)	$ (14,286)
Denominator:		
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	9,699,721	9,693,254
Assumed exchange of Class B Common Stock [1]	23,115,631	23,119,246
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	32,815,352	32,812,500
Adjusted proforma earnings per fully exchanged share, basic and diluted	$ (0.30)	$ (0.44)

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

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