

# vTv Therapeutics Reports 2017 Fourth Quarter and Full Year Financial and Operational Results and Recent Highlights

# 02/27/18

HIGH POINT, N.C.--(BUSINESS WIRE)--Feb. 27, 2018-- <u>vTv Therapeutics Inc.</u> (Nasdaq:VTVT) today provided a corporate update and reported financial and operational results for the fourth quarter and full year that ended December 31, 2017.

"We made tremendous progress across the spectrum of our Alzheimer's and diabetes programs this past year, and look forward to continuing this momentum in 2018 as we anticipate reporting topline results in April from Part A of our Phase 3 STEADFAST study of azeliragon in patients with mild Alzheimer's disease," said Steve Holcombe, president and CEO of vTv Therapeutics. "Our unique and holistic approach to targeting Alzheimer's through the receptor for advanced glycation endproducts (RAGE) antagonist addresses three major pathologies believed to contribute to the disease: transport of a-beta to the brain, inflammation and the phosphorylation of tau protein. We're hopeful that results from the study will be a step toward finding a much-needed therapy for the Alzheimer's community and the millions of people suffering from this devastating disease."

# Fourth Quarter 2017 Highlights

#### vTv Therapeutics Initiates Phase 1b/2 Study as Part of Industry Partnership with the Juvenile Diabetes Research Foundation (JDRF)

Conducted with support from JDRF, the leading global organization funding type 1 diabetes (T1D) research, vTv
Therapeutics initiated simplici-T1, an adaptive Phase1b/2 study assessing the pharmacokinetics, pharmacodynamics,
safety and tolerability of vTv Therapeutics' liver-selective glucokinase activator, TTP399, in type 1 diabetes. The study will
evaluate whether TTP399 is well-tolerated when administered as an add-on to insulin therapy and can improve daily
glucose profiles and HbA1c in people living with T1D.

#### vTv Therapeutics and Hangzhou Zhongmei Huadong Pharmaceutical Co. Enter Licensing Agreement for GLP-1r Diabetes Program

vTv Therapeutics successfully entered into a licensing agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., one of the largest pharmaceutical companies in China, for rights to develop and commercialize vTv Therapeutics' GLP-1r agonist program, including TTP273, in China and other Pacific Rim countries. vTv Therapeutics received an \$8 million upfront payment and is eligible for up to an additional \$75 million in milestone payments related to development, regulatory and commercialized products in the licensed territories. vTv will conduct a Phase 2 multi-region clinical trial, including sites in both the United States and China, to investigate the safety and efficacy of a lower dose of TTP273 in patients with type 2 diabetes.

#### vTv Therapeutics and Reneo Pharmaceuticals Enter Licensing Agreement for PPAR-delta Program

 vTv Therapeutics granted Reneo Pharmaceuticals exclusive worldwide rights to research, develop and commercialize vTv Therapeutics' selective peroxisome proliferator-activated receptor delta (PPAR-delta) program, including HPP593, in a global licensing agreement. Under the terms of the agreement, vTv Therapeutics received an upfront payment and is eligible to receive future development and commercialization milestones as well as royalties on sales of approved products. vTv Therapeutics also received shares of Reneo Pharmaceuticals' common stock.

# vTv Therapeutics Hosts Key Opinion Leader (KOL) Event on Current State of Clinical Development in Alzheimer's Disease

 vTv Therapeutics hosted a KOL presentation focused on the current state of clinical development in Alzheimer's disease. The event featured two speakers with extensive experience in Alzheimer's research and care: Dr. Howard Fillit, founding executive director and chief scientific officer of Alzheimer's Drug Discovery Foundation, clinical professor of geriatric medicine, palliative care and neuroscience at Mt. Sinai School of Medicine; and Dr. Mary Sano, associate dean for clinical research, professor of psychiatry, founding member and director of the Alzheimer's Disease Research Center at Mt. Sinai School of Medicine. vTv Therapeutics provided a brief overview of the company's ongoing Phase 3 clinical development program for azeliragon, an orally bioavailable small molecule RAGE antagonist for patients with mild Alzheimer's disease.

## **Upcoming Anticipated Milestones**

• vTv Therapeutics anticipates reporting topline data from Part A of the company's Phase 3 STEADFAST Study in April 2018. Data from Part B are expected to read out in early 2019. The STEADFAST study is a single protocol within which vTv Therapeutics is conducting two statistically independent, identical, randomized, double-blind, placebo-controlled trials investigating the efficacy of azeliragon as a potential treatment of mild Alzheimer's disease.

# Shelf Registration on Form S-3

• Today the Company filed a S-3 Registration Statement with the Securities and Exchange Commission to register Class A Common Stock. The Company has no current plans to issue securities under the Registration Statement.

## Fourth Quarter 2017 Financial Results

- Cash Position: Cash and cash equivalents as of December 31, 2017, were \$11.8 million compared to \$20.5 million as of September 30, 2017.
- **R&D Expenses**: Research and development expenses were \$10.1 million in the fourth quarter of 2017, compared to \$9.0 million in the third quarter of 2017. The increase in research and development expense was primarily driven by increased enrollment in the open-label extension trial and higher consulting costs incurred related to the STEADFAST Study.
- **G&A Expenses**: General and administrative expenses were \$2.9 million and \$2.6 million, for the fourth and third quarters of 2017, respectively. The increase in general and administrative cost was primarily due to the higher professional service fees incurred in the fourth quarter of 2017 related to our license agreements entered into in December 2017.
- Net Loss Before Non-Controlling Interest: Net loss before non-controlling interest was \$14.6 million for the fourth quarter of 2017 compared to net loss before non-controlling interest of \$12.4 million for the third quarter of 2017.
- Net Loss per Share: GAAP net loss per share was \$0.44 and \$0.38 for the three months ended December 31, 2017 and September 30, 2017, respectively, based on weighted-average shares of 9.7 million in each period. Non-GAAP net loss per fully exchanged share was \$0.44 and \$0.38 for the three months ended December 31, 2017 and September 30, 2017, respectively, based on non-GAAP fully exchanged weighted-average shares of 32.8 million in each period.

#### Full Year 2017 Financial Results

- **R&D Expenses**: Research and development expenses were \$39.6 million in 2017, compared to \$45.7 million in 2016. The decrease in research and development expense was primarily driven by decreases in clinical trial costs for TTP399 and TTP273 as both the AGATA and LOGRA studies were completed in 2016. Additionally, we saw decreases in the expense for *azeliragon* as a result of the completion of drug-drug interaction and other supporting studies in 2016 which were partially offset by increases in cost related to continuing enrollment in the open-label extension trial and increased cost of consultants engaged to assist with the STEADFAST Study.
- **G&A Expenses**: General and administrative expenses were \$11.3 million and \$9.9 million, for the 2017 and 2016, respectively. The increase in general and administrative cost was primarily due to the higher professional service fees incurred in 2017 related to our license agreements entered into in December 2017 and increased compensation cost related to the grant of additional share-based compensation awards as well as the impact of additional personnel hired in both years.
- Net Loss Before Non-Controlling Interest: Net loss before non-controlling interest was \$54.6 million for 2017 compared to net loss before non-controlling interest of \$55.4 million for 2016.
- Net Loss per Share: GAAP net loss per share was \$1.67 and \$1.71 for 2017 and 2016, respectively, based on weightedaverage shares of 9.7 million and 9.5 million in each period, respectively. Non-GAAP net loss per fully exchanged share was \$1.67 and \$1.69 for 2017 and 2016, respectively, based on non-GAAP fully exchanged weighted-average shares of 32.8 million in each period.

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

	December 31, 2017	September 30, 2017 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,758	\$ 20,488
Restricted cash and cash equivalents	162	281

Accounts receivable, net	8,000	_
Prepaid expenses and other current assets	442	725
Total current assets	20,362	21,494
Restricted cash and cash equivalents, long-term	2,500	_
Property and equipment, net	283	310
Long-term investments	2,480	—
Long-term deposits	2,292	2,251
Total assets	\$ 27,917	\$ 24,055
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 13,901	\$ 10,120
Deferred revenue	8,757	—
Current portion of notes payable	4,271	2,083
Total current liabilities	26,929	12,203
Notes payable	15,316	17,228
Deferred revenue, net of current portion	4,497	—
Warrant liability, related party	492	—
Other liabilities	290	285
Total liabilities	47,524	29,716
Commitments and contingencies		
Redeemable noncontrolling interest	131,440	130,642
Stockholders' deficit:		
Class A Common Stock	97	97
Class B Common Stock	232	232
Additional paid-in capital	127,682	127,036
Accumulated deficit	(279,058	) (263,668
Total stockholders' deficit attributable to vTv Therapeutics Inc.	(151,047	) (136,303
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	\$ 27,917	\$ 24,055

# vTv Therapeutics Inc.

# Condensed Consolidated Statements of Operations - Unaudited

(in thousands, except per share data)

	т	Three Months Ended			
				September 3	0,
	D	ecember 31, 2017	,	2017	
Revenue	\$	233		\$ 15	
Operating expenses:					
Research and development		10,068		8,989	
General and administrative		2,937		2,567	
Total operating expenses		13,005		11,556	
Operating loss		(12,772	)	(11,541	)
Interest income		22		35	
Interest expense		(852	)	(849	)
Other expense, net		(190	)	_	
Loss before income taxes and noncontrolling interest		(13,792	)	(12,355	)
Income tax provision		800		—	
Net loss before noncontrolling interest		(14,592	)	(12,355	)
Less: net loss attributable to noncontrolling interest		(10,281	)	(8,705	)
Net loss attributable to vTv Therapeutics Inc.	\$	(4,311	)	\$ (3,650	)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	\$	(0.44	)	\$ (0.38	)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	ł	9,693,254		9,693,254	

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

) )

	December (Unaudite		1,		Decembe	r 3'	1,	
	2017		2016		2017		2016	
Revenue	\$233		\$ 38		\$291		\$634	
Operating expenses:								
Research and development	10,068		11,099		39,640		45,748	
General and administrative	2,937		2,252		11,333		9,906	
Total operating expenses	13,005		13,351		50,973		55,654	
Operating loss	(12,772	)	(13,313	)	(50,682	)	(55,020	)
Interest income	22		20		117		87	
Interest expense	(852	)	(394	)	(3,092	)	(398	)
Other expense, net	(190	)	(24	)	(190	)	(22	)
Loss before income taxes and noncontrolling interest	(13,792	)	(13,711	)	(53,847	)	(55,353	)
Income tax provision	800		_		800		—	
Net loss before noncontrolling interest	(14,592	)	(13,711	)	(54,647	)	(55,353	)
Less: net loss attributable to noncontrolling interest	(10,281	)	(9,661	)	(38,503	)	(39,001	)
Net loss attributable to vTv Therapeutics Inc.	\$ (4,311	)	\$ (4,050	)	\$ (16,144	)	\$(16,352	)
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	\$ (0.44	)	\$ (0.42	)	\$ (1.67	)	\$(1.71	)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	9,693,25	54	9,693,25	4	9,693,25	4	9,545,52	27

#### 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 includes two statistically independent, identical, randomized, double-blind, placebo-controlled Phase 3 trials, investigating the efficacy of azeliragon as a potential treatment to slow the decline in cognition and functional activities for patients with mild Alzheimer's disease. The 18-month study targeted enrollment of 800 patients (400 each for Part A and B). Part A enrolled patients in the United States and Canada. Enrollment of Part B additionally included study sites in the United Kingdom, Ireland, Australia, New Zealand and South Africa. Subjects completing the STEADFAST study are eligible to enroll in a 24-month open-label extension trial. STEADFAST is being conducted following agreement with FDA under the Special Protocol Assessment (SPA) process and the azeliragon development program has been granted fast track designation. Enrollment of Part A was completed in September 2016 with data anticipated to read out in April 2018. Part B data is expected to read out in early 2019.

# **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 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

#### **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		
	December 31, 2017	September 30, 2017	
Numerator:			
Net loss attributable to vTv Therapeutics Inc.	\$ (4,311	) \$ (3,650	)
Reallocation of net income attributable to non-controlling interest from the assumed exchange of Class B shares (1)	(10,281	) (8,705	)
Net loss before noncontrolling interest Denominator:	\$ (14,592	) \$ (12,355	)
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	9,693,254	9,693,254	
Assumed exchange of Class B Common Stock (1)	23,119,246	23,119,246	
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	32,812,500	32,812,500	
Adjusted proforma earnings per fully exchanged share, basic and diluted	\$ (0.44	) \$ (0.38	)

	Three Months Ended December 31,		Twelve Months December 31,	s Ended
	2017	2016	2017	2016
Numerator: Net loss attributable to $vTv$ Therapeutics Inc.	\$ (4,311 )	\$ (4,050 )	\$ (16,144 )	\$ (16,352 )
Reallocation of net income attributable to non-controlling interest from the assumed exchange of Class B shares $^{(1)}$	(10,281)	(9,661)	(38,503)	(39,001)
Net loss before noncontrolling interest Denominator:	\$ (14,592 )	\$(13,711)	\$ (54,647 )	\$ (55,353 )
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	9,693,254	9,693,254	9,693,254	9,545,527
Assumed exchange of Class B Common Stock (1)	23,119,246	23,119,246	23,119,246	23,266,973
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	32,812,500	32,812,500	32,812,500	32,812,500
Adjusted proforma earnings per fully exchanged share, basic and diluted	\$ (0.44 )	\$(0.42)	\$(1.67)	\$(1.69)

(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.

View source version on businesswire.com: http://www.businesswire.com/news/home/20180227006693/en/

Source: vTv Therapeutics Inc.

Investors: vTv Therapeutics Inc. Mike Biega, 617-221-9660 IR@vtvtherapeutics.com or Media: W2O pure Katie Engleman, 910-509-3977 Kengleman@w2ogroup.com