

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (date of earliest event reported): **November 8, 2018**

vTv Therapeutics Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37524
(Commission File No.)

47-3916571
(IRS Employer
Identification No.)

**4170 Mendenhall Oaks Pkwy
High Point, NC 27265**
(Address of principal executive offices)

(336) 841-0300
(Registrant's telephone number, including area code)

NOT APPLICABLE
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On November 8, 2018, vTv Therapeutics Inc. issued a press release to announce its financial results for the fiscal quarter ended September 30, 2018. A copy of the press release is attached as Exhibit 99.1 to this current report on Form 8-K and is incorporated herein by reference.

The information in this report (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of Section 18, of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 8, 2018, announcing financial results for the fiscal quarter ended September 30, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

VTV THERAPEUTICS INC.

By: /s/ Rudy C. Howard
Name: Rudy C. Howard
Title: Chief Financial Officer

Dated: November 8, 2018



vTv Therapeutics Announces Third Quarter 2018 Results and Update

HIGH POINT, N.C. – (BUSINESS WIRE) – Nov. 8, 2018 – [vTv Therapeutics Inc.](#) (Nasdaq:VTVT) today reported financial results for the third quarter that ended September 30, 2018, and provided an update on recent achievements and upcoming events.

“We continue to believe in the therapeutic potential of *azelinagon* and are committed to finding the optimal development pathway forward for the program,” said Steve Holcombe, chief executive officer, vTv Therapeutics. “We are also making progress with our other programs, either internally in the case of our GKA program, or through our licensing partners for our GLP-1R agonist, PPAR-delta, and PDE4 programs. We hope to see milestones achieved for each of these programs during 2019.”

Recent Achievements and Outlook

- **Presentation of data at 11th Clinical Trials on Alzheimer’s Disease.** Presented positive post-hoc subgroup data indicating a potential benefit of treatment with *azelinagon* in Alzheimer’s disease patients with type 2 diabetes. This subgroup included 55 patients with glycosylated hemoglobin (HbA1c) of greater than 6.5% at baseline (HbA1c greater than 7.7% was an exclusion criterion at screening) and a clinical diagnosis of Alzheimer’s disease in the combined A-Study and B-Study of the STEADFAST trial. The *azelinagon*-treated group in the A-Study (n=18) demonstrated a 6.1 point benefit on ADAS-cog relative to the placebo group (n=8), which was nominally statistically significant ($p = 0.005$), and a 1.7 point benefit on CDR-sb relative to placebo ($p = 0.08$) after 18 months of treatment.
- **Meeting with European Medicines Agency.** Met with the Scientific Advice Working Party (SAWP) of the EMA on October 30, 2018, to discuss future development requirements in support of seeking regulatory approval of *azelinagon* in the European Union. We expect to receive formal guidance from the SAWP during the fourth quarter of 2018.
- **SimplicT-1 Study enrolling patients with type 1 diabetes.** The adaptive Phase 1/2 SimplicT-1 Study continues to enroll patients with type 1 diabetes in a 12-week study to evaluate TTP399 as an add-on to insulin therapy. We expect to have an interim read-out of the results of this study in early 2019. TTP399 has previously demonstrated statistically significant reductions in HbA1c levels in the AGATA Study, a phase 2 study in type 2 diabetes.

Upcoming Events

vTv will participate in the following upcoming investor conferences:

- Piper Jaffray 30th Annual Healthcare Conference, November 27-29, New York, NY.
 - J.P. Morgan 37th Annual Healthcare Conference, January 7-10, San Francisco, CA.
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Second Quarter 2018 Financial Results

- **Cash Position:** Cash and cash equivalents as of September 30, 2018, were \$3.8 million compared to \$1.2 million as of June 30, 2018.
 - **R&D Expenses:** Research and development expenses were \$2.7 million in the third quarter of 2018, compared to \$8.6 million in the second quarter of 2018. The decrease in research and development expenses was primarily driven by the termination of the STEADFAST and open label extension studies during the second quarter of 2018.
 - **G&A Expenses:** General and administrative expenses were \$2.2 million and \$2.7 million, for the third quarter of 2018 and the second quarter of 2018, respectively. General and administrative expenses were lower due to reduced share-based compensation expense and professional service fees.
 - **Net Loss Before Non-Controlling Interest:** Net loss before non-controlling interest was \$2.0 million for the third quarter of 2018 compared to net loss before non-controlling interest of \$9.6 million for the second quarter of 2018.
 - **Net Loss Per Share:** GAAP net loss per share was \$0.06 and \$0.31 for the three months ended September 30, 2018 and June 30, 2018, respectively, based on weighted-average shares of 12.3 million and 10.0 million for the three month periods ended September 30, 2018 and June 30, 2018, respectively. Non-GAAP net loss per fully exchanged share was \$0.06 and \$0.29 for the three months ended September 30, 2018 and June 30, 2018, respectively, based on non-GAAP fully exchanged weighted-average shares of 35.4 million and 33.1 million for the three months ended September 30, 2018 and June 30, 2018, respectively.
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vTv Therapeutics Inc.
Condensed Consolidated Balance Sheets - Unaudited
(in thousands)

	<u>September 30,</u> <u>2018</u>	<u>June 30,</u> <u>2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,766	\$ 1,163
Restricted cash and cash equivalents	—	—
Accounts receivable, net	—	2,270
Prepaid expenses and other current assets	1,006	264
Current deposits	1,124	2,311
Total current assets	5,896	6,008
Restricted cash and cash equivalents, long-term	2,500	2,500
Property and equipment, net	177	202
Long-term investments	2,480	2,480
Long-term deposits	36	36
Total assets	\$ 11,089	\$ 11,226
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,965	\$ 13,144
Current portion of deferred revenue	6,747	10,114
Current portion of notes payable	9,597	8,229
Total current liabilities	25,309	31,487
Notes payable	8,611	10,863
Deferred revenue, net of current portion	595	603
Warrant liability, related party	382	201
Other liabilities	258	256
Total liabilities	35,155	43,410
Commitments and contingencies		
Redeemable noncontrolling interest	19,912	39,413
Stockholders' deficit:		
Class A Common Stock	158	109
Class B Common Stock	232	232
Additional paid-in capital	144,617	134,587
Accumulated deficit	(188,985)	(206,525)
Total stockholders' deficit attributable to vTv Therapeutics Inc.	(43,978)	(71,597)
Total liabilities, redeemable noncontrolling interest and stockholders' deficit	\$ 11,089	\$ 11,226

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

	Three Months Ended	
	September 30, 2018	June 30, 2018
Revenue	\$ 3,375	\$ 2,473
Operating expenses:		
Research and development	2,698	8,594
General and administrative	2,158	2,737
Total operating expenses	<u>4,856</u>	<u>11,331</u>
Operating loss	(1,481)	(8,858)
Interest income	13	16
Interest expense	(822)	(870)
Other income (expense), net	329	316
Loss before income taxes and noncontrolling interest	(1,961)	(9,396)
Income tax provision	—	200
Net loss before noncontrolling interest	(1,961)	(9,596)
Less: net loss attributable to noncontrolling interest	(1,165)	(6,524)
Net loss attributable to vTv Therapeutics Inc.	<u>\$ (796)</u>	<u>\$ (3,072)</u>
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.31)</u>
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	<u>12,305,949</u>	<u>10,049,831</u>

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,	
	2018	2017	2018	2017
Revenue	\$ 3,375	\$ 15	\$ 7,912	\$ 58
Operating expenses:				
Research and development	2,698	8,989	20,235	29,572
General and administrative	2,158	2,567	7,150	8,396
Total operating expenses	<u>4,856</u>	<u>11,556</u>	<u>27,385</u>	<u>37,968</u>
Operating loss	(1,481)	(11,541)	(19,473)	(37,910)
Interest income	13	35	47	95
Interest expense	(822)	(849)	(2,547)	(2,240)
Other income (expense), net	329	—	656	—
Loss before income taxes and noncontrolling interest	(1,961)	(12,355)	(21,317)	(40,055)
Income tax provision	—	—	200	—
Net loss before noncontrolling interest	(1,961)	(12,355)	(21,517)	(40,055)
Less: net loss attributable to noncontrolling interest	(1,165)	(8,705)	(14,697)	(28,222)
Net loss attributable to vTv Therapeutics Inc.	<u>\$ (796)</u>	<u>\$ (3,650)</u>	<u>\$ (6,820)</u>	<u>\$ (11,833)</u>
Net loss per share of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.38)</u>	<u>\$ (0.64)</u>	<u>\$ (1.22)</u>
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	<u>12,305,949</u>	<u>9,693,254</u>	<u>10,701,599</u>	<u>9,693,254</u>

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 (A-Study and B-Study), was designed to investigate the safety and efficacy of *azeliagon* 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. While in April and in June 2018 topline results were announced that the A-Study and the B-Study did not meet the co-primary endpoints and clinical trials were ended, subsequent post-hoc subgroup analyses have shown populations that experienced positive benefits.

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	
	September 30, 2018	June 30, 2018
Numerator:		
Net loss attributable to vTv Therapeutics Inc.	\$ (796)	\$ (3,072)
Reallocation of net income attributable to non-controlling interest from the assumed exchange of Class B shares ⁽¹⁾	(1,165)	(6,524)
Net loss before noncontrolling interest	<u>\$ (1,961)</u>	<u>\$ (9,596)</u>
Denominator:		
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	12,305,949	10,049,831
Assumed exchange of Class B Common Stock ⁽¹⁾	<u>23,114,652</u>	<u>23,094,221</u>
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	<u>35,420,601</u>	<u>33,144,052</u>
Adjusted proforma earnings per fully exchanged share, basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.29)</u>

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss attributable to vTv Therapeutics Inc.	\$ (796)	\$ (3,650)	\$ (6,820)	\$ (11,833)
Reallocation of net income attributable to non-controlling interest from the assumed exchange of Class B shares ⁽¹⁾	(1,165)	(8,705)	(14,697)	(28,222)
Net loss before noncontrolling interest	<u>\$ (1,961)</u>	<u>\$ (12,355)</u>	<u>\$ (21,517)</u>	<u>\$ (40,055)</u>
Denominator:				
Weighted-average number of vTv Therapeutics Inc. Class A Common Stock, basic and diluted	12,305,949	9,693,254	10,701,599	9,693,254
Assumed exchange of Class B Common Stock ⁽¹⁾	<u>23,114,652</u>	<u>23,119,246</u>	<u>23,101,279</u>	<u>23,119,246</u>
Adjusted proforma fully exchanged weighted-average shares of Class A common stock outstanding, basic and diluted	<u>35,420,601</u>	<u>32,812,500</u>	<u>33,802,878</u>	<u>32,812,500</u>
Adjusted proforma earnings per fully exchanged share, basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.38)</u>	<u>\$ (0.64)</u>	<u>\$ (1.22)</u>

(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.

Contacts

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