## 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): August 10, 2016

### 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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o 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))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 8.01 Other Events

On August 10, 2016, vTv Therapeutics Inc. (the "Company") issued a press release announcing positive topline results from a placebo and active-comparator-controlled Phase 2b clinical study of TTP399, a liver-selective glucokinase activator under development for the treatment of Type 2 diabetes.

Topline results showed achievement of the primary endpoint of statistically significant change from baseline in HbA1c at 6 months of daily administration of 800 mg of TTP399. The reduction in HbA1c was dose-dependent and sustained throughout the duration of the study. TTP399 was also found to be well-tolerated. Further analysis of the data is ongoing.

The Phase 2b AGATA (Add Glucokinase Activator to Target A1c) is a six-month, double-blind, placebo- and active-controlled parallel group trial in 190 patients with Type 2 diabetes on a stable dose of metformin. The primary endpoint was change from baseline in HbA1c at six months. 190 subjects with Type 2 diabetes were enrolled and randomized into four arms, and 110 subjects remained in the trial through completion. 26 subjects received a daily dose of 800 mg of TTP399 for the full six-month course of treatment.

A copy of the press release is attached as Exhibit 99.1.

#### Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1 Press Release dated August 10, 2016

#### **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 Rudy C. Howard Name: Title: Chief Financial Officer

Dated: August 10, 2016



## vTv Therapeutics Announces Positive Topline Results from Phase 2b Study of Glucokinase Activator TTP399 in Type 2 Diabetes

Novel glucokinase activator shows sustained meaningful reduction in HbA1c with well-tolerated treatment regimen

**High Point, NC – August 10, 2016** – vTv Therapeutics Inc. (Nasdaq: VTVT), a clinical-stage biopharmaceutical company engaged in discovery and development of new orally administered treatments for Alzheimer's disease and diabetes, today announced positive topline results from a placebo and active-comparator-controlled Phase 2b clinical study of TTP399, a liver-selective glucokinase activator under development for the treatment of Type 2 diabetes.

Topline results showed achievement of the primary endpoint of statistically significant change from baseline in HbA1c at 6 months of daily administration of 800 mg of TTP399. The reduction in HbA1c was dose-dependent and sustained throughout the duration of the study. TTP399 was also found to be well-tolerated. Further analysis of the data is ongoing.

"We are extremely pleased with these findings from our Phase 2b study of TTP399," commented Steve Holcombe, President and CEO of vTv Therapeutics. "These results show that a glucokinase activator with hepatic selectivity may lead to a meaningful reduction in HbA1c on a sustained basis. We are enthusiastic about advancing TTP399 to the next stage of development."

"We now have a glucokinase activator that appears to improve glucose control in a safe and sustained manner. I believe the Phase 2 results suggest that TTP399 may become a significant treatment option in diabetes care," said Dr. John Buse, Director of the North Carolina Translational and Clinical Sciences Institute and of the Diabetes Center at the University of North Carolina School of Medicine and a member of the vTv Therapeutics Scientific Advisory Board.

The Phase 2b AGATA (Add Glucokinase Activator to Target A1c) is a six-month, double-blind, placebo- and active-controlled parallel group trial in 190 patients with Type 2 diabetes on a stable dose of metformin. The primary endpoint was change from baseline in HbA1c at six months.

A manuscript with more details is in preparation and will be submitted for publication to a major medical journal.

#### **About Glucokinase and TTP399**

Glucokinase (GK) is a key regulator of glucose homeostasis. GK is a genetically validated target. Loss of function mutations in the gene coding for GK can cause hyperglycemia and Type 2 diabetes.

Activation of GK, a mechanism of action that is distinct from existing Type 2 diabetes treatments, increases GK activity thereby improving glycemic control in Type 2 diabetes. Previous attempts to develop GK activators were unsuccessful due to lack of sustained clinical effect, and increased incidence of hypoglycemia and hyperlipidemia. TTP399 is an orally bioavailable small molecule GK activator. Unlike previous approaches, TTP399 targets GK activation only in the liver and does not appear to disrupt the interaction between GK and glucokinase regulatory protein (GKRP). TTP399 was discovered by vTv scientists using its proprietary translational technology platform.

#### **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 Type 2 diabetes as well as treatment of inflammatory disorders and the prevention of muscle weakness.

#### **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.

#### **Investors**

The Trout Group Michael Gibralter 646-378-2938 mgibralter@troutgroup.com

#### Media

BMC Communications Brad Miles 646-513-3125 bmiles@bmccommunications.com