vTv Therapeutics Announces 2024 Second Quarter Financial Results and Provides Corporate Update

August 8, 2024

Screened first patient in cadisegliatin pivotal trial for type 1 diabetes (T1D); working to resolve clinical hold

Expanded Newsoara Biopharma license agreement for PDE4 inhibitor HPP737 to a global license effective upon payment of the $20 million upfront fee

HIGH POINT, N.C., Aug. 08, 2024 (GLOBE NEWSWIRE) -- vTv Therapeutics Inc. (Nasdaq: VTVT), a late-stage biopharmaceutical company with an innovative clinical portfolio of small molecules and lead program in diabetes, today reported financial results for the second quarter ended June 30, 2024, and provided an update on recent corporate developments.

"Our small molecule portfolio continues to make significant progress across our partnered and Company driven programs. We were pleased to amend our license with Newsoara Biopharma for PDE4 inhibitor, *HPP737,* to make it a global license contingent upon receipt of the required upfront fee. *Azeliragon,* a Cantex-partnered program, recently received Orphan Drug Designation in pancreatic cancer and is advancing in several mid- to late-stage clinical trials with broad indication potential," said Paul Sekhri, Chairman, President and Chief Executive Officer of vTv Therapeutics. "We were pleased to initiate our pivotal trial in T1D for c*adisegliatin,* our liver selective glucokinase activator with first-in-class potential in T1D. We are working to resolve our clinical hold and resume the study as quickly as possible. *Cadisegliatin* has shown a favorable safety profile and has been dosed in over 500 subjects to date, including 300 patients with type 1 and type 2 diabetes. We are encouraged at the potential of *cadisegliatin* as an oral therapy for improved glycemic control."

Recent Company Highlights

- **Screened First Patient in *Cadisegliatin* Pivotal Trial for T1D.** In June, vTv Therapeutics screened the first patient in the Company's CATT1 pivotal trial evaluating *cadisegliatin* as an adjunct treatment of T1D. CATT1 is one of several trials that are planned to form the core of the future regulatory registrational submission for *cadisegliatin*, a potential first-in-class, oral, liver selective, glucokinase activator for T1D. In July, vTv Therapeutics announced the Food and Drug Administration (FDA) placed a clinical hold on the *cadisegliatin* clinical program following the discovery of a chromatographic signal in a recent human absorption, distribution, metabolism, and excretion (ADME) study of *cadisegliatin* that could not be resolved by standard mass spectroscopy. The FDA requires a single *in vitro* study to characterize this signal before the *cadisegliatin* program can resume. No patient was dosed in the CATT1 pivotal study at the time of the clinical hold, and past clinical studies did not reveal any clinically concerning safety issues. vTv Therapeutics is actively working with the FDA to resolve the clinical hold as quickly as possible. *Cadisegliatin* has previously been granted Breakthrough Therapy designation by the FDA for T1D and has shown clinical potential to improve glycemic control and reduce hypoglycemia in patients with diabetes.
- **Expanded to a Global Licensing Agreement for *HPP737* with Newsoara Biopharma.** In June, vTv Therapeutics amended our license with Newsoara Biopharma for PDE4 inhibitor, *HPP737,* to make it a global license upon receipt of the required $20 million upfront fee. The terms of the amendment include up to $41 million in development milestones, up to $35 million in sales-related milestones, and royalties in the mid to upper single digits based on sales.
- **Orphan Drug Designation Granted for *Azeliragon*.** In May, Cantex Pharmaceuticals, Inc. announced that the FDA has granted Orphan Drug Designation to *azeliragon*, a well-tolerated once-a-day oral RAGE antagonist, for the treatment of pancreatic cancer. *Azeliragon* has also received Orphan Drug Designation for the treatment of glioblastoma. Under our license agreement with Cantex, vTv Therapeutics has the potential to receive 20 – 40% of out licensing income or the fair value of the program in the event of a sale of Cantex, or 20% of Cantex's net profit from commercial sales. Cantex is evaluating *azeliragon* in several ongoing Phase 2 trials in cancer indications and one Phase 3 trial for acute kidney injury.

Second Quarter 2024 Financial Results

- **Cash Position**: The Company's cash position as of June 30, 2024, was $45.5 million compared to $9.4 million as of December 31, 2023. The increase is attributed to receipt of the proceeds from the private placement financing on February 27, 2024.
- **Research & Development (R&D) Expenses**: R&D expenses were $3.4 million and $4.7 million in each of the three months ended June 30, 2024, and 2023, respectively. The decrease of $1.3 million is primarily attributable to lower spending on *cadisegliatin,* due to decreases in toxicity study costs and drug manufacturing related costs, partially offset by increases in clinical trial start-up costs and an increase in indirect costs and other projects.
- **General & Administrative (G&A) Expenses:** G&A expenses were $3.7 million and $3.3 million for each of the three months ended June 30, 2024, and 2023, respectively. The increase of $0.4 million was primarily due to increases in share-based expense, legal expense and higher payroll costs, partially offset by lower other G&A costs.
- **Other Income, Net**: Other income for the three months ended June 30, 2024, was $0.2 million and was driven by gains

related to the change in the fair value of the outstanding warrants to purchase shares of our own stock. Other income for the three months ended June 30, 2023, was $0.6 million and was driven by an unrealized gain related to our investment in Reneo, as well as gains related to the change in the fair value of the outstanding warrants to purchase shares of our own stock issued to related parties.

- **Net Loss**: Net loss attributable to vTv shareholders for the three months ended June 30, 2024, was $5.2 million or $0.81 per basic share. Net loss attributable to vTv shareholders for the comparable period a year ago was $5.6 million or $2.69 per basic share.

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

	June 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 45,526	$ 9,446
Accounts receivable	306	102
Prepaid expenses and other current assets	303	1,044
Current deposits	65	65
Total current assets	46,200	10,657
Property and equipment, net	72	117
Operating lease right-of-use assets	186	244
Total assets	$ 46,458	$ 11,018
Liabilities, Redeemable Noncontrolling Interest and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,791	$ 10,242
Current portion of operating lease liabilities	177	169
Current portion of contract liabilities	17	17
Current portion of notes payable	—	191
Total current liabilities	6,985	10,619
Contract liabilities, net of current portion	18,669	18,669
Operating lease liabilities, net of current portion	79	169
Warrant liability, related party	158	110
Warrant liability	130	—
Total liabilities	26,021	29,567
Commitments and contingencies		
Redeemable noncontrolling interest	—	6,131
Stockholders' equity (deficit):		
Class A Common Stock	24	21
Class B Common Stock	6	6
Additional paid-in capital	307,746	256,335
Accumulated deficit	(291,301)	(281,042)
Total stockholders' equity (deficit) attributable to vTv Therapeutics Inc.	16,475	(24,680)
Noncontrolling interest	3,962	—
Total stockholders' equity (deficit)	20,437	(24,680)
Total liabilities, redeemable noncontrolling interest and stockholders' equity (deficit)	$ 46,458	$ 11,018

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Revenue	$ —	$ —	$ 1,000	$ —
Operating expenses:				
Research and development	3,439	4,691	6,088	8,633
General and administrative	3,716	3,309	7,694	6,794
Total operating expenses	7,155	8,000	13,782	15,427
Operating loss	(7,155)	(8,000)	(12,782)	(15,427)
Interest income	553	153	632	253
Other income (expense), net	193	638	(178)	2,191
Loss before income taxes and noncontrolling interest	(6,409)	(7,211)	(12,328)	(12,985)
Income tax provision	—	—	100	—
Net loss before noncontrolling interest	(6,409)	(7,211)	(12,428)	(12,985)
Less: net loss attributable to noncontrolling interest	(1,229)	(1,592)	(2,383)	(2,867)
Net loss attributable to vTv Therapeutics Inc.	$ (5,180)	$ (5,619)	$ (10,045)	$ (10,118)
Net loss attributable to vTv Therapeutics Inc. common shareholders	$ (5,180)	$ (5,619)	$ (10,045)	$ (10,118)
Net loss per share of vTv Therapeutics Inc. Class A common stock, basic and diluted (*)	$ (0.81)	$ (2.69)	$ (1.97)	$ (4.85)
Weighted average number of vTv Therapeutics Inc. Class A common stock, basic and diluted (*)	6,403,444	2,084,973	5,098,877	2,084,973

(*) Adjusted retroactively for reverse stock split

About vTv Therapeutics

vTv Therapeutics Inc. is a late-stage biopharmaceutical company focused on developing oral, small molecule drug candidates. vTv's clinical pipeline is led by *cadisegliatin*, a potential adjunctive therapy to insulin for the treatment of type 1 diabetes. vTv and its development partners are investigating additional indications including type 2 diabetes and other chronic conditions.

Forward-Looking Statement

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 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 our forward-looking statements by these cautionary statements.

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