Vigil Neuroscience Reports Second Quarter 2023 Financial Results and Provides Business Update

Aug 08, 2023

- Interim data from 20 mg/kg cohort in IGNITE Phase 2 clinical trial of VGL101 in people living with ALSP expected in fourth quarter of 2023 -

- Small molecule TREM2 agonist IND submission and initiation of Phase 1 clinical trial on track for fourth quarter of 2023 -

- Appoints drug development veteran Christopher J. Silber, M.D. as Chief Medical Officer -

WATERTOWN, Mass., Aug. 08, 2023 (GLOBE NEWSWIRE) -- Vigil Neuroscience, Inc. (Nasdaq: VIGL), a clinical-stage biotechnology company committed to harnessing the power of microglia for the treatment of neurodegenerative diseases, today announced financial results for the second quarter ended June 30, 2023, and provided an update on its recent progress.

“During the quarter, we continued to advance our lead candidates for ALSP and Alzheimer's Disease and are well-positioned to deliver on multiple value-driving milestones in the second half of 2023,” said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. “Most notably, we are on track to provide interim data from IGNITE, our ongoing Phase 2 trial evaluating VGL101 in people living with ALSP. This interim analysis will include the first six patients following six months of treatment. Together with data from our ongoing Natural History Study, ILLUMINATE, this analysis may provide further observations relating to the trajectory of the disease and could be instrumental in validating key therapeutic biomarkers to support proof-of-concept of VGL101.”

“In addition to VGL101, we have also made significant progress with our novel small molecule TREM2 agonist for the potential treatment of Alzheimer’s Disease. We are on track to submit an IND application and initiate a Phase 1 clinical trial in healthy volunteers in the fourth quarter of 2023,” concluded Dr. Magovčević-Liebisch. “Driven by our mission to bring transformative therapies to patients with both rare and common neurodegenerative diseases, we are thrilled by our continued progress advancing our pipeline.”

Recent Highlights and Anticipated Milestones

VGL101, a monoclonal antibody TREM2 agonist

- **Added 40 mg/kg dose cohort in ongoing IGNITE Phase 2 clinical trial:** IGNITE, the first-ever interventional trial in people living with ALSP, is a global Phase 2, open-label clinical trial designed to evaluate the safety and tolerability of VGL101 in up to 15 patients with symptomatic ALSP who have a *CSF1R* gene mutation. The Company has added a dose cohort in which patients will receive an intravenous (IV) infusion of VGL101 at 40 mg/kg approximately every four weeks, for a treatment duration of one year in addition to the initial dose cohort of 20 mg/kg.
- **First interim data readout from 20 mg/kg cohort in ongoing IGNITE Phase 2 clinical trial expected in the fourth quarter of 2023:** The Phase 2 clinical trial evaluating VGL101 in people living with ALSP is ongoing and the Company remains on track to report interim data in the fourth quarter of 2023 from the first 6 patients at 6 months who have received 20 mg/kg of VGL101.
- **Full data analysis from the VGL101 Phase 1 single and multiple ascending dose (SAD and MAD) healthy volunteer trial expected in the second half of 2023:** The Company has completed dosing of the 60 mg/kg SAD and MAD cohorts in which VGL101 continued to be safe and well-tolerated and expects to report the full data analysis from the Phase 1 clinical trial in the third quarter of 2023 at an upcoming medical conference.
- **Continued patient-focused initiatives for ALSP community:** As previously disclosed in May 2023, Vigil launched ALSPAware, a new genetic testing and counseling initiative designed to enable improved patient diagnosis of ALSP. Developed with both patients and healthcare providers in mind, the program includes a single gene confirmatory test for individuals with a family history of ALSP, as well as a custom gene panel available for physicians to use in diagnosing adult-onset neurological diseases, including ALSP.

Small Molecule TREM2 Agonist Program

- **Continued to progress small molecule TREM2 agonist program toward clinical development:** The Company expects to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) and, subject to FDA clearance of the IND, initiate clinical development in healthy volunteers for its lead small molecule TREM2 agonist in the fourth quarter of 2023. The program will have an initial focus on genetically defined subpopulations of Alzheimer’s Disease. Vigil’s highly active, selective and brain-penetrant small molecule agonists are designed to act as a molecular glue that potentiates the TREM2 signaling response to natural damage ligands. In preclinical studies, Vigil has established that its small molecule agonists demonstrate on-target TREM2 activation across both common and rare TREM2 variants.

Additionally, the Company has demonstrated that its small molecule agonists were able to deliver *in vivo* TREM2 responses within the central nervous system at a magnitude and specificity similar to VGL101.

- **Presented at Keystone Symposia on Molecular and Cellular Biology – Neurodegeneration: New Biology Guiding the Next Generation of Therapeutic Development:** In May 2023, Vigil presented a poster and an oral presentation on the unique mechanism of action of its small molecule TREM2 agonists for the potential treatment of Alzheimer's Disease. The presentations can be accessed on the publications page of the Company's website.

Corporate

- **Appointment of drug development veteran Christopher J. Silber, M.D. as Chief Medical Officer:** The Company recently announced the appointment of Christopher J. Silber, M.D. as Chief Medical Officer. Dr. Silber brings over 30 years of biopharmaceutical industry experience and a track record of clinical and regulatory success developing novel therapeutics in neuroscience.

Second Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities were $150.2 million as of June 30, 2023, compared to $164.5 million as of March 31, 2023. The Company expects its cash, cash equivalents and marketable securities to fund its operational plans into the first quarter of 2025.
- **Research and Development** (**R&D) Expenses:** R&D expenses for the second quarter ended June 30, 2023, were $14.9 million, compared to $12.1 million for the same period in 2022. This increase was primarily driven by increased preclinical activity related to the Company's small molecule program, increased clinical trial-related expenses associated with the continued advancement of the VGL101 program, and increased headcount to support the Company's continued growth.
- **General and Administrative** (**G&A) Expenses:** G&A expenses for the second quarter ended June 30, 2023, were $7.0 million, compared to $4.9 million for the same period in 2022. The increase was primarily attributable to increases in headcount-related costs to support the Company's growth.
- **Net Loss:** Loss from operations for the second quarter ended June 30, 2023, were $20.2 million, compared to $17.0 million for the same period in 2022.

About Vigil Neuroscience

Vigil Neuroscience is a clinical-stage biotechnology company focused on developing treatments for both rare and common neurodegenerative diseases by restoring the vigilance of microglia, the sentinel immune cells of the brain. We are utilizing the tools of modern neuroscience drug development across multiple therapeutic modalities in our efforts to develop precision-based therapies to improve the lives of patients and their families. VGL101, our lead clinical candidate, is a fully human monoclonal antibody agonist targeting human triggering receptor expressed on myeloid cells 2 (TREM2) in people with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP), a rare and fatal neurodegenerative disease. We are also developing a novel small molecule TREM2 agonist to treat common neurodegenerative diseases associated with microglial dysfunction, with an initial focus on Alzheimer's disease (AD) in genetically defined subpopulations.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements" of Vigil Neuroscience's ("Vigil" or the "Company") that are made pursuant to the safe harbor provisions of the federal securities laws, including, without limitation, express or implied statements regarding: the Company's strategy, business plans, focus and value of future milestones; the progress and timing of the preclinical and clinical development of Vigil's programs, including the availability of data and expected timing for reporting interim data from IGNITE Phase 2 clinical trial, filing an IND application for its small molecule TREM2 agonist program and the initiation of the Phase 1 clinical trial and reporting full data analysis from its Phase 1 healthy volunteer trial of VGL101; the success and timing of its interactions with regulatory authorities; and the Company's cash runway into first quarter of 2025. Forward-looking statements are based on Vigil's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to uncertainties inherent in the identification and development of product candidates, including the conduct of research activities and the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results and data from preclinical and clinical studies; the timing of the Company's ability to submit and obtain regulatory clearance for investigational new drug applications and initiate additional clinical trials; whether results from preclinical studies and clinical studies will be predictive of the results of later preclinical studies and clinical trials; the Company's ability to initiate and complete its current and expected clinical trials; whether Vigil's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission (SEC), including Vigil's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, its upcoming Quarterly Report on Form 10-Q for the quarter-ended June 30, 2023 and in any subsequent filings Vigil makes with the SEC. Forward-looking statements contained in this announcement are made as of this date, and Vigil undertakes no duty to update such information except as required under applicable law. Readers should not rely upon the information on this page as current or accurate after its publication date.

VIGIL NEUROSCIENCE, INC.
Consolidated Statements of Operations

(in thousands, except share and per share data)
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Operating expenses:				
Research and development	$ 14,903	$ 12,097	$ 28,737	$ 22,462
General and administrative	7,010	4,945	13,951	9,912
Total operating expenses	21,913	17,042	42,688	32,374
Loss from operations	(21,913)	(17,042)	(42,688)	(32,374)
Other income (expense):				
Interest income, net	1,746	32	2,731	34
Other income (expense), net	(7)	(5)	(12)	(9)
Total other income (expense), net	1,739	27	2,719	25
Net loss	$ (20,174)	$ (17,015)	$ (39,969)	$ (32,349)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (0.60)	$ (1.04)	$ (1.18)
Weighted—average common shares outstanding, basic and diluted	38,657,205	28,150,051	38,601,916	27,409,264

VIGIL NEUROSCIENCE, INC.
Selected Balance Sheet Data
(in thousands)
(unaudited)

	June 30, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 150,164	$ 186,605
Total assets	175,409	200,393
Total liabilities	21,573	11,312
Total stockholders' equity	153,836	189,081

Investor Contact: Leah Gibson Vice President, Investor Relations & Corporate Communications Vigil Neuroscience, Inc. lgibson@vigilneuro.com
Media Contact: Megan McGrath MacDougall Advisors mmcgrath@macdougall.bio