Vigil Neuroscience Reports Second Quarter 2024 Financial Results and Provides Business Update

Aug 13, 2024

- Announced $40 million strategic investment from Sanofi; Extended cash runway into 2026 -

- Provided update on iluzanebart clinical development strategy to pursue potential accelerated approval pathway in ALSP -

- Announced interim data from VG-3927 Phase 1 trial in healthy volunteers that support continued development as potential therapy for Alzheimer's disease -

WATERTOWN, Mass., Aug. 13, 2024 (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, 2024, and provided an update on recent progress.

"Vigil has made great progress in the first half of this year as we continue to advance our pipeline of novel candidates for indications with strong genetic links to microglial dysfunction," said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. "With the recent strategic investment from Sanofi and our clinical program updates that support an encouraging regulatory pathway for iluzanebart in ALSP and the continued development of VG-3927 for the potential treatment of AD, we believe that we are well-positioned to execute on our strategy to bring these potentially transformative therapies to patients and their families."

Recent Highlights and Anticipated Milestones

Iluzanebart, Monoclonal Antibody TREM2 Agonist:

- **Clinical development strategy update following Type C Meeting with U.S. Food and Drug Administration (FDA):** In July 2024, the Company announced that it updated the clinical development strategy for iluzanebart. This follows a Type C meeting with the FDA where the Agency stated it was open to considering the accelerated approval pathway and that the Company should provide additional data to support the proposed development plan. The updated strategy includes preserving the IGNITE dataset for a final analysis at 12 months, which the Company believes provides an opportunity to leverage its biomarker strategy and to pursue the potential accelerated approval pathway.
- **Final analysis from IGNITE clinical trial planned for first half of 2025:** The Company plans to report the final analysis from the IGNITE clinical trial, including all patients at 12 months dosed with either 20 mg/kg or 40 mg/kg of iluzanebart in the first half of 2025.
- **Publication on ALSP Genetic Mutation Prevalence in Neurology Genetics:** In July 2024, a peer-reviewed research publication reported new data on the prevalence and clinical significance of *CSF1R* gene variants in the UK population. The research, published in the journal *Neurology Genetics* and conducted by Wade *et al*., suggests the estimated prevalence of ALSP is underreported in the U.S., EU, and UK. Prior to this publication, it was estimated there may be approximately 10,000 people living with ALSP in the U.S. with similar prevalence outside of the U.S. Based on these new data, the Company now estimates U.S. prevalence of ALSP is approximately 19,000 while the estimated combined EU and UK prevalence is approximately 29,000.

VG-3927, Small Molecule TREM2 Agonist

- **Interim data from ongoing Phase 1 clinical trial evaluating VG-3927 in healthy volunteers:** In July 2024, the Company reported interim data from the ongoing Phase 1 SAD/MAD clinical trial evaluating VG-3927 in healthy volunteers. These data showed that the safety and tolerability profile observed in individual doses in six SAD and two MAD cohorts supports continued clinical development of VG-3927. In addition, VG-3927 demonstrated a predictable PK profile supportive of once-daily dosing. Importantly, in the SAD and MAD cohorts, VG-3927 achieved a robust and sustained decrease of soluble TREM2 in the CSF demonstrating clinical proof-of-target engagement. VG-3927 also showed an increase in osteopontin/secreted phosphoprotein 1 (SPP1) after repeat dosing.
- **Complete Phase 1 clinical data in first quarter of 2025:** As part of the Phase 1 clinical trial, the Company has commenced screening for a cohort of AD patients, including some participants who carry TREM2 or other disease-related variants to explore the biomarker response of VG-3927 after a single dose. Vigil expects to use these data to inform the development strategy for subsequent and larger trials evaluating VG-3927 in AD. The Company plans to report the complete Phase 1 clinical data, including data from the AD patient cohort, in the first quarter of 2025.

Corporate

- **$40 million strategic investment from Sanofi:** In June 2024, the Company entered into a Securities Purchase Agreement with Sanofi, a global healthcare and pharmaceutical company, pursuant to which Vigil agreed to issue an aggregate of 537,634 Series A non-voting preferred shares, each convertible into 10 shares of common stock, at an as-converted price of $7.44 per common share for gross proceeds of $40 million. The Company plans to use the proceeds to fund its research and development activities.

Second Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities were $86.7 million as of June 30, 2024, compared to $101.6 million as of March 31, 2024. The Company expects its cash, cash equivalents and marketable securities, together with the $40 million gross proceeds received from Sanofi in July, will fund its operational plans into 2026.
- **Research and Development** (**R&D) Expenses:** R&D expenses for the second quarter ended June 30, 2024, were $15.5 million, compared to $14.9 million for the same period in 2023. This increase was driven by advancing VG-3927 Phase 1 clinical development and headcount-related costs to support the Company's continued growth.
- **General and Administrative** (**G&A) Expenses:** G&A expenses for the second quarter ended June 30, 2024, were $6.9 million, consistent with the $7.0 million for the same period in 2023.
- **Net Loss:** Loss from operations for the second quarter ended June 30, 2024, were $21.2 million, compared to $20.2 million for the same period in 2023.

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. Vigil is utilizing the tools of modern neuroscience drug development across multiple therapeutic modalities in its efforts to develop precision-based therapies to improve the lives of patients and their families. Iluzanebart, Vigil's 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. Vigil is also developing VG-3927, a novel small molecule TREM2 agonist, to treat common neurodegenerative diseases associated with microglial dysfunction, with an initial focus on Alzheimer's disease (AD) patients, including some who carry TREM2 and other disease-associated variants.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements" of Vigil Neuroscience ("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 and focus; the potential therapeutic benefit of the Company's product candidates, including VG-3927, and the expected therapeutic benefits of such programs as well as the ability to improve the lives of patients and their families; the estimated prevalence of ALSP in the US, UK and EU; the progress and timing of the clinical development of Vigil's programs, including the availability of, and expected timing for reporting, data from both the IGNITE Phase 2 clinical trial and the VG-3927 Phase 1 clinical trial; beliefs about observations made analyzing preclinical study and clinical trial data to date; the success and timing of the Company's interactions with regulatory authorities, including with the FDA regarding the accelerated approval pathway; and the expectation that the Company's cash runway will be sufficient into 2026. 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 development of product candidates, including the conduct of research activities and the conduct of clinical trials; uncertainties as to the availability and timing of results and data from clinical trials; whether results from prior preclinical studies and clinical trials will be predictive of the results of subsequent preclinical studies and clinical trials; the timing and content of additional regulatory information from the FDA; the Company's ability to work with the FDA to successfully remove the partial clinical hold on VG-3927; 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, 2024, its upcoming Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 and 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, 2024	June 30, 2023	June 30, 2024	June 30, 2023
Operating expenses:				
Research and development	$ 15,540	$ 14,903	$ 29,866	$ 28,737
General and administrative	6,938	7,010	14,027	13,951
Total operating expenses	22,478	21,913	43,893	42,688
Loss from operations	(22,478)	(21,913)	(43,893)	(42,688)

Other income (expense):				
Interest income, net	1,254	1,746	2,731	2,731
Other income (expense), net	(3)	(7)	(5)	(12)
Total other income, net	1,251	1,739	2,726	2,719
Net loss	$ (21,227)	$ (20,174)	$ (41,167)	$ (39,969)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (0.52)	$ (1.02)	$ (1.04)
Weighted—average common shares outstanding, basic and diluted	40,564,580	38,657,205	40,214,345	38,601,916

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents, and marketable securities	$ 86,674	$ 117,940
Total assets	108,464	140,858
Total liabilities	23,192	24,606
Total stockholders' equity	85,272	116,252

Internet Posting of Information
Vigil Neuroscience routinely posts information that may be important to investors in the 'Investors' section of its website at https://www.vigilneuro.com. The company encourages investors and potential investors to consult our website regularly for important information about Vigil Neuroscience.

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