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

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- Final analysis from IGNITE Phase 2 clinical trial evaluating iluzanebart in ALSP planned for first half of 2025 -

- Data from Phase 1 clinical trial evaluating VG-3927 in Alzheimer's Disease on track for first quarter of 2025 -

WATERTOWN, Mass., Nov. 07, 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 third quarter ended September 30, 2024, and provided an update on recent progress.

"Our accomplishments in the third quarter have provided significant momentum as we continue to progress our two differentiated TREM2 agonists through clinical development with the goal of reaching patients as quickly as possible," said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. "We believe our strategic positioning of iluzanebart in ALSP and VG-3927 in Alzheimer's disease creates two distinct opportunities to establish TREM2 as a therapeutic target and novel pathway for treating neurodegenerative diseases. Our focus remains on execution as we advance closer to important data milestones for our programs in 2025."

Recent Highlights and Upcoming 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. 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.
- **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.
- **Final analysis from IGNITE Phase 2 clinical trial planned for first half of 2025:** The Company plans to report the final analysis from the IGNITE Phase 2 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.

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 single- and multiple-ascending dose 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 supported continued clinical development of VG-3927. In addition, VG-3927 demonstrated a predictable PK profile supportive of once-daily dosing. Importantly, 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.
- **Presented new preclinical and clinical data at 2024 Alzheimer's Association International Conference (AAIC):** In July 2024, the Company presented one oral and two poster presentations highlighting VG-3927 and its small molecule TREM2 agonist program at AAIC. The oral presentation included new clinical data from the ongoing Phase 1 clinical trial of VG-3927 for the treatment of Alzheimer's disease (AD). The posters highlighted the Phase 1 study design and the functional characterization of VG-3927 as a TREM2 specific, highly potent oral small molecule. The presentation and posters can be accessed on the Publications page of the Company's website.
- **Dosing initiated in Alzheimer's disease cohort in ongoing Phase 1 clinical trial:** As part of the Phase 1 clinical trial, the Company initiated dosing of 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.

- **Removal of partial clinical hold:** In September 2024, the Company announced that the FDA had removed the partial clinical hold on its ongoing Phase 1 clinical trial of VG-3927. The FDA's decision was based on a complete response submitted by the Company.
- **Complete Phase 1 clinical data of VG-3927 on track for first quarter of 2025:** Vigil is on track to report the complete Phase 1 clinical data of VG-3927, including data from the AD patient cohort, in the first quarter of 2025.

Third Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities were $111.3 million as of September 30, 2024, compared to $86.7 million as of June 30, 2024. The Company expects its cash, cash equivalents and marketable securities will fund its operational plans into 2026.
- **Research and Development (R&D) Expenses:** R&D expenses for the third quarter ended September 30, 2024, were $13.8 million, compared to $15.4 million for the same period in 2023. The decrease was driven by the timing of manufacturing activities for iluzanebart partially offset by an increase in VG-3927 Phase 1 clinical development as well as headcount-related costs.
- **General and Administrative (G&A) Expenses:** G&A expenses for the third quarter ended September 30, 2024, were $6.9 million, consistent with the $6.9 million for the same period in 2023.
- **Net Loss:** Net loss for the third quarter ended September 30, 2024, was $19.3 million, compared to $20.5 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 iluzanebart and VG-3927, and the expected therapeutic benefits of such programs as well as the ability to improve the lives of patients and their families; beliefs about 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 timing and outcomes 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; 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 June 30, 2024, its upcoming Quarterly Report on Form 10-Q for the quarter ended September 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		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Operating expenses:				
Research and development	$ 13,772	$ 15,415	$ 43,638	$ 44,152

General and administrative	6,904	6,906	20,931	20,857
Total operating expenses	20,676	22,321	64,569	65,009
Loss from operations	(20,676)	(22,321)	(64,569)	(65,009)
Other income (expense):				
Interest income, net	1,410	1,829	4,141	4,560
Other income (expense), net	8	(3)	3	(15)
Total other income, net	1,418	1,826	4,144	4,545
Net loss	$ (19,258)	$ (20,495)	$ (60,425)	$ (60,464)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.47)	$ (0.53)	$ (1.50)	$ (1.56)
Weighted—average common shares outstanding, basic and diluted	40,577,955	38,809,109	40,336,433	38,671,739

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents, and marketable securities	$ 111,269	$ 117,940
Total assets	131,273	140,858
Total liabilities	42,721	24,606
Total stockholders' equity	88,552	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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