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): November 7, 2023

VIGIL NEUROSCIENCE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-41200**	**85-1880494**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Vigil Neuroscience, Inc.
100 Forge Road, Suite 700
Watertown, Massachusetts 02472
(Address of principal executive offices, including zip code)

(857) 254-4445
(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:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ 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))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trade Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	VIGL	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 7, 2023, Vigil Neuroscience, Inc. issued a press release announcing its financial results for the three months ended September 30, 2023 (the "Press Release"). A copy of the Press Release is furnished herewith as Exhibit 99.1.

The information set forth under Item 2.02 and in Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated November 7, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Vigil Neuroscience, Inc.

Date: November 7, 2023

By: /s/ Ivana Magovčević-Liebisch
Ivana Magovčević-Liebisch
President and Chief Executive Officer

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

– Interim data from 20 mg/kg cohort in IGNITE Phase 2 clinical trial of VGL101 in ALSP on track for this quarter –

– First participant dosed in Phase 1 study of VG-3927, the first and only small molecule TREM2 agonist in clinical development for potential treatment of Alzheimer's disease –

– Announced VGL101 complete Phase 1 data analysis and Phase 2 IGNITE trial design at 2023 ANA Annual Meeting –

WATERTOWN, Mass., November 7, 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 third quarter ended September 30, 2023, and provided an update on recent progress.

"We continue to make significant progress in advancing our novel TREM2 agonist candidates—VGL101 in ALSP and VG-3927 in Alzheimer's disease, and believe we are well-positioned to become a leader in neurodegenerative drug development," said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. "Importantly, we are diligently advancing our Phase 2 IGNITE trial, the first interventional study in ALSP, and expect to report our interim results from the first six patients treated for six months with VGL101 this quarter. In September, we also proudly introduced our oral small molecule TREM2 agonist candidate, VG-3927, with the opening of our IND. We dosed our first participant in our Phase 1 clinical trial in healthy volunteers last month and expect to share interim results in mid-2024."

"As the only company known to have two TREM2 modalities, we have achieved critical milestones to support our mission to bring transformative therapies to patients with both rare and common neurodegenerative diseases," added Dr. Magovčević-Liebisch. "With our unique precision medicine approach and dedicated team of industry leaders, we look forward to the continued development of our clinical programs to serve patient populations with high unmet need."

Recent Highlights and Anticipated Milestones

VGL101, A Fully Human Monoclonal Antibody TREM2 Agonist

- **First interim data readout from 20 mg/kg cohort in ongoing IGNITE Phase 2 clinical trial on track for this quarter:** The Phase 2 clinical trial evaluating VGL101 in adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP) is ongoing and the Company remains on track to report interim data this quarter from the first 6 patients at 6 months who have received 20 mg/kg of VGL101.
- **Presented complete data analysis from Phase 1 single and multiple ascending dose (SAD and MAD) healthy volunteer trial and Phase 2 study design via two posters at ANA 2023:** In September 2023, the Company presented the complete data analysis from its Phase 1 healthy volunteer trial, showing that VGL101 demonstrated a favorable safety and tolerability profile in SAD and MAD cohorts at doses up to 60 mg/kg. VGL101 showed linear and predictable pharmacokinetic (PK) characteristics and an observed half-life that supports monthly dosing. Target engagement and downstream pharmacodynamic responses of VGL101 at 20 mg/kg and 40 mg/kg support evaluating these doses in the ongoing IGNITE Phase 2 trial in ALSP. The Company also presented the trial design for its ongoing Phase 2 IGNITE study, a global, open-label clinical trial evaluating VGL101 in approximately 15 patients with symptomatic ALSP who have a confirmed *CSF1R* gene mutation. These presentations can be accessed on the publications page of the Company's website.
- **Granted Orphan Drug Designation for VGL101 from the European Medicines Agency (EMA):** In October 2023, the European Commission granted orphan drug designation for VGL101 for the treatment of *CSF1R*-related leukoencephalopathy, which includes ALSP. In July 2022, VGL101 was granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for ALSP.
- **Continued patient-focused initiatives for ALSP community:** In October, the Company added a new section for healthcare providers (HCPs) on ALSPinfo.com, a disease education website for ALSP. Prior to the update, ALSPinfo.com included information and resources for those living with ALSP and their caregivers. By expanding the website to include an HCP section, the Company hopes to continue to raise awareness for ALSP, lower the frequency of misdiagnosis, and encourage the utilization of genetic testing for diagnostic purposes.

VG-3927, An Oral Small Molecule TREM2 Agonist

- **First participant dosed in ongoing Phase 1 clinical trial in healthy volunteers:** In October 2023, the first participant was dosed in the Phase 1 clinical trial in healthy volunteers evaluating VG-3927. VG-3927 is the first and only oral small molecule TREM2 agonist in clinical development for the potential treatment of Alzheimer's disease (AD). The Company expects to report interim Phase 1 topline data for VG-3927 in healthy volunteers in mid-2024.
- **Update on small molecule program and hosted R&D Event**: In September 2023, the Company was informed by the FDA that the Investigational New Drug (IND) application for VG-3927 was open and the Phase 1 clinical trial in healthy volunteers was allowed to proceed with a partial clinical hold related to maximum exposure limit. The FDA subsequently indicated that additional non-clinical data is needed in order to exceed the maximum exposure limit set by the FDA in the Phase 1 clinical trial. The Company is in the process of obtaining additional PK data and will work

with the FDA to address the partial clinical hold. Based on preclinical studies, the Company believes that the maximum exposure limit exceeds the predicted efficacious dose of VG-3927. At this time, the Company does not anticipate delays in the current clinical development plans for VG-3927.

In September 2023, the Company hosted an R&D Event to share details on VG-3927 with KOL guest participation from Marco Colonna, M.D. and Samuel Gandy, M.D. The event highlighted new preclinical data for VG-3927, discussed current treatment approaches for AD, and Vigil's TREM2-focused clinical approach for treating AD guided by its precision medicine strategy. A recording of the event can be accessed on the Events & Presentations page of the Investors Section of the Company's website.

Third Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities were $133.6 million as of September 30, 2023, compared to $150.2 million as of June 30, 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 third quarter ended September 30, 2023, were $15.4 million, compared to $12.8 million for the same period in 2022. The increase was primarily driven by increased manufacturing-related expenses associated with the VGL101 program, increased clinical activity associated with advancing the VG-3927 program into a Phase 1 clinical trial, and increased headcount to support the Company's continued growth.
- **General and Administrative (G&A) Expenses:** G&A expenses for the third quarter ended September 30, 2023, were $6.9 million, compared to $4.8 million for the same period in 2022. The increase was primarily attributable to increases in headcount-related costs and professional service fees to support the Company's growth.
- **Net Loss:** Loss from operations for the third quarter ended September 30, 2023, were $20.5 million, compared to $17.5 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 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) in genetically defined subpopulations.

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 progress and timing of the clinical development of Vigil’s programs, including the availability of, and expected timing for reporting, interim data from both the IGNITE Phase 2 clinical trial and the VG-3927 Phase 1 clinical trial; the anticipated impact of the VG-3927 partial clinical hold on the Company’s clinical development plans, regulatory progress and clinical progress for VG-3927; the success and timing of the Company’s 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 conduct of clinical trials; uncertainties as to the availability and timing of results and data from clinical trials; whether results from preclinical studies and clinical trials will be predictive of the results of later 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 June 30, 2023, its upcoming Quarterly Report on Form 10-Q for the quarter ended September 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.

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.

VIGIL NEUROSCIENCE, INC.
Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Operating expenses:				
Research and development	$ 15,415	$ 12,791	$ 44,152	$ 35,253
General and administrative	6,906	4,846	20,857	14,758
Total operating expenses	22,321	17,637	65,009	50,011

Loss from operations	(22,321)	(17,637)	(65,009)	(50,011)
Other income (expense):				
Interest income, net	1,829	163	4,560	197
Other income (expense), net	(3)	(26)	(15)	(35)
Total other income (expense), net	1,826	137	4,545	162
Net loss	$ (20,495)	$ (17,500)	$ (60,464)	$ (49,849)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.53)	$ (0.53)	$ (1.56)	$ (1.70)
Weighted—average common shares outstanding, basic and diluted	38,809,109	33,303,345	38,671,739	29,395,548

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 133,643	$ 186,605
Total assets	159,156	200,393
Total liabilities	23,320	11,312
Total stockholders' equity	135,836	189,081

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