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): March 26, 2024

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 March 26, 2024, Vigil Neuroscience, Inc. issued a press release announcing its financial results for the three months and year ended December 31, 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 March 26, 2024
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: March 26, 2024

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

Vigil Neuroscience Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

– Reported positive interim data from Phase 2 IGNITE proof-of-concept clinical trial evaluating iluzanebart (VGL101) for treatment of ALSP;

- Enrollment for IGNITE trial completed with 20 patients enrolled; Next data readout planned for Q3 2024 –

– Phase 1 healthy volunteer clinical trial evaluating VG-3927 ongoing; Interim data analysis on track for mid-2024 –

– Appointed Biotech Industry Executive Petra Kaufmann, M.D., M.S., F.A.A.N, as Chief Medical Officer –

WATERTOWN, Mass., March 26, 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 fourth quarter and full year ended December 31, 2023, and provided an update on recent progress.

"Among our many recent milestones, the most significant for Vigil was the positive data readout from our ongoing Phase 2 IGNITE trial and ILLUMINATE natural history study. Findings from these studies have provided critical insights and a rich dataset on biomarkers that we believe support our strategy to advance iluzanebart through clinical development as quickly as possible. We are also pleased to have enrolled 20 patients in our IGNITE trial, exceeding our target of 15 patients. This is a true testament to the importance of our mission to bring a novel therapy to ALSP patients," said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. "Our Phase 1 clinical trial evaluating VG-3927 in healthy volunteers is progressing as planned and we are on track to provide an interim data readout in mid-2024. As the first and only clinical-stage small molecule TREM2 agonist, bringing our next-generation candidate into the clinic is a landmark achievement for the Company and for the Alzheimer's disease treatment landscape. We look forward to further progressing our two TREM2 modalities through clinical development in 2024."

Recent Highlights and Anticipated Milestones

Iluzanebart, Monoclonal Antibody TREM2 Agonist

- **Positive interim data from Phase 2 IGNITE proof-of-concept clinical trial evaluating iluzanebart in patients with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP):** The Phase 2 interim data readout, evaluating 6 patients at 6 months dosed with 20 mg/kg,

demonstrated that iluzanebart had a favorable tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) profile consistent with iluzanebart Phase 1 data for 20 mg/kg in healthy volunteers. Importantly, iluzanebart showed clear target engagement as measured by changes in soluble TREM2 (sTREM2), soluble CSF1R (sCSF1R), and osteopontin in cerebral spinal fluid (CSF). Individual ALSP patients treated with iluzanebart also demonstrated directionally supportive changes in magnetic resonance imaging (MRI) and neurofilament light chain (NfL) biomarkers. Enrollment for IGNITE is completed with 20 patients enrolled in the trial, which exceeds the initially planned 15 patients. The next data analysis from IGNITE is planned for the third quarter of 2024 at which time the Company expects to provide 12-month follow-up data from patients in the 20 mg/kg dose cohort and data from patients in the 40 mg/kg dose cohort who have completed 6 months.

- **Important insights observed from ILLUMINATE, the first natural history study in ALSP:** Additional observations from the ILLUMINATE study have demonstrated a correlation between MRI biomarkers and cognitive changes in ALSP patients at 12 months. Using the Montreal Cognitive Assessment (MoCA) scale, data analysis showed a statistically significant correlation between increased ventricular volume and lower MoCA scores in symptomatic ALSP patients, both indicating disease worsening. In addition, a statistically significant relationship between loss of gray matter volume and reduction in MoCA scores were observed, which are also indicative of disease worsening. These relationships may support the use of changes in ventricular volume and gray matter volume as biomarkers of disease progression.

VG-3927, Oral Small Molecule TREM2 Agonist

- **Phase 1 clinical trial in healthy volunteers ongoing:** The Phase 1 clinical trial evaluating VG-3927, the first and only small molecule TREM2 agonist in the clinic for the potential treatment of Alzheimer's disease (AD), commenced dosing in October 2023 and is proceeding with a partial clinical hold from the FDA related to maximum exposure limit. The Company is working 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 and does not anticipate any delay in its current development plans for VG-3927. An interim data readout from the trial is planned for mid-2024. The Company plans to include a cohort of AD patients in the Phase 1 trial to explore a biomarker response of VG-3927. The Company plans to include genetically defined AD subpopulations with microglia dysfunction in this cohort, including those who carry TREM2 and other variants and expects to use these data to inform patient selection and the development strategy for its subsequent larger trials in AD.

Corporate

- **Appointment of biotech industry executive Petra Kaufmann, M.D., M.S., F.A.A.N, as Chief Medical Officer:** The Company recently announced the appointment of Petra Kaufmann, M.D., M.S., F.A.A.N, as Chief Medical Officer. Dr. Kaufmann brings over 30 years of expertise in neurological and rare diseases and a track record of global drug development in transformative and innovative therapies.

Fourth Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities were $117.9 million as of December 31, 2023, compared to $133.6 million as of September 30, 2023. In January 2024, the Company announced that it extended its projected cash runway into the second half of 2025.
- **Research and Development (R&D) Expenses:** R&D expenses were $16.8 million for the fourth quarter and $60.9 million for the year ended December 31, 2023, compared to $12.2 million and $47.4 million for the same periods in 2022. This increase year-over-year was primarily driven by increased preclinical and clinical activity related to advancing VG-3927 into a Phase 1 clinical trial in October 2023, increased clinical trial and manufacturing related expenses associated with the Phase 2 clinical trial of iluzanebart, and increases in headcount-related costs to support the advancement of the Company's clinical development programs.
- **General and Administrative (G&A) Expenses:** G&A expenses were $7.1 million for the fourth quarter and $27.9 million for the year ended December 31, 2023, compared to $6.7 million and $21.4 million for the same periods in 2022. The increase year-over-year was primarily attributable to increases in headcount-related costs and professional service fees to support the Company's growth.
- **Net Loss:** Loss from operations were $22.2 million for the fourth quarter and $82.6 million for the year ended December 31, 2023, compared to $18.5 million and $68.3 million for the same periods in 2022. The increase year-over-year was attributable to higher operating costs in the current period to support the advancement of the Company's pipeline, which was partially offset by increases in interest income from investments.

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) 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, 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 anticipated impact of the VG-3927 partial clinical hold on the Company's clinical development plans and beliefs about the maximum exposure limit, regulatory

progress and clinical progress for VG-3927; the success and timing of the Company's interactions with regulatory authorities; and the expectation that the Company's cash runway will be sufficient into the second half 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 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 September 30, 2023, its upcoming Annual Report on Form 10-K for the year ended December 31, 2023 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.

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		Year Ended	
	December 31, 2023	December 31, 2022	December 31, 2023	December 31, 2022
Operating expenses:				
Research and development	$ 16,782	$ 12,191	$ 60,934	$ 47,444
General and administrative	7,075	6,682	27,932	21,440
Total operating expenses	23,857	18,873	88,866	68,884
Loss from operations	(23,857)	(18,873)	(88,866)	(68,884)
Other income (expense):				
Interest income, net	1,681	426	6,241	623
Other income (expense), net	2	(9)	(13)	(44)
Total other income (expense), net	1,683	417	6,228	579
Net loss	$ (22,174)	$ (18,456)	$ (82,638)	$ (68,305)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (0.48)	$ (2.13)	$ (2.16)
Weighted - average common shares outstanding, basic and diluted	38,832,292	38,479,196	38,712,207	31,685,125

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

	December 31, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	$ 117,940	$ 186,605
Total assets	140,858	200,393
Total liabilities	24,606	11,312
Total stockholders' equity	116,252	189,081

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