

**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): May 10, 2023

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

Delaware
(State or other jurisdiction
of incorporation)

001-41200
(Commission
File Number)

85-1880494
(I.R.S. Employer
Identification No.)

Vigil Neuroscience, Inc.
100 Forge Rd, 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 May 10, 2023, Vigil Neuroscience, Inc. issued a press release announcing its financial results for the three months ended March 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 May 10, 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: May 10, 2023

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

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

- *Partial clinical hold lifted by FDA on VGL101 -*

- *Launched ALSPAware to provide access to no-cost genetic testing and counseling for ALSP -*

- *Appointed distinguished biopharmaceutical industry leader, Samantha Budd Haeberlein, Ph.D., to Board of Directors -*

- *Interim data from IGNITE Phase 2 clinical trial of VGL101 in patients with ALSP expected in the fourth quarter of 2023 -*

- *Small molecule TREM2 agonist IND submission and initiation of the Phase 1 clinical trial planned for the fourth quarter of 2023 -*

- *On track to report full data analysis from Phase 1 healthy volunteer trial of VGL101 in the second half of 2023 -*

WATERTOWN, Mass., May 10, 2023 – 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 first quarter ended March 31, 2023, and provided an update on recent progress.

“We continue to make considerable progress in advancing VGL101 and our small molecule TREM2 agonist program and believe we are well-positioned to execute on multiple value enhancing milestones in 2023. Our IGNITE Phase 2 trial evaluating VGL101 in patients with ALSP is enrolling as expected and we plan to report our first interim update from the first six patients treated for six months with VGL101 in the fourth quarter of this year. We also remain on track to present the full data analysis from the VGL101 Phase 1 trial in the second half of this year. In addition, we are proud of the recent launch of *ALSPAware* as part of our continued efforts to support the ALSP community. Given that only one-third of those living with ALSP receive a correct initial diagnosis, we believe this new program will help both physicians and individuals reach an accurate diagnosis earlier,” said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. “We have also continued to advance our lead small molecule candidate toward the clinic and expect to submit an IND and initiate a Phase 1 trial in healthy volunteers in the fourth quarter of 2023. We are committed to achieving these important milestones as part of our patient-centered mission of developing potentially transformative treatments for rare and common neurodegenerative diseases.”

Recent Highlights and Anticipated Milestones

VGL101, Monoclonal Antibody TREM2 Agonist

- **Announced FDA lifted partial clinical hold on doses greater than 20 mg/kg for VGL101:** In March 2023, Vigil announced that the U.S. Food and Drug Administration (FDA) lifted its partial clinical hold on doses greater than 20 mg/kg for VGL101 in its ongoing and future clinical trials in patients with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP).

- **Presented multiple presentations on ALSP at the 2023 American Academy of Neurology (AAN) Annual Meeting:** In April 2023, Vigil presented three oral presentations and two poster presentations on ALSP, including previously reported VGL101 Phase 1 interim top-line data and the ILLUMINATE natural history study interim data. The Company also presented key findings on the diverse phenotype, radiological features, and reasons for misdiagnosis and disease progression of ALSP. These presentations can be accessed on the publications page of the Company's website.
- **Launched *ALSPAware* program to provide access to no-cost genetic testing and counseling for ALSP:** 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. By increasing access to genetic testing for both individuals and healthcare providers, we believe *ALSPAware* has the potential to help reduce initial misdiagnosis of this disease, while also providing appropriate disease management services for those living with ALSP.
- **On track to present the full data analysis from the Phase 1 single and multiple ascending dose (SAD and MAD) healthy volunteer trial in the second half of 2023:** The Company has completed dosing of the 60 mg/kg SAD and MAD cohorts in Australia in which VGL101 continued to be safe and well tolerated and expects to report the full data analysis from the Phase 1 trial during the second half of 2023.
- **First interim data readout from ongoing IGNITE Phase 2 clinical trial expected in the fourth quarter of 2023:** IGNITE, the first-ever interventional trial in ALSP, is a global Phase 2, open-label trial designed to evaluate the safety and tolerability of VGL101 in up to 15 patients with symptomatic ALSP who have a *CSF1R* gene mutation. Patients enrolled in the trial receive an intravenous (IV) infusion of 20 mg/kg of VGL101 approximately every four weeks, for a treatment duration of one year. The Company expects to report six-month interim data from the first six patients in the trial in the fourth quarter of 2023.

Small Molecule TREM2 Agonist Program

- **Presented small molecule TREM2 agonist program preclinical data at the AD/PD, Alzheimer's & Parkinson's Diseases International Conference:** In April 2023, Vigil presented an oral presentation highlighting preclinical data from the characterization of its small molecule TREM2 agonist program supporting further development as a potential treatment of Alzheimer's disease (AD). This presentation can be accessed on the publications page of the Company's website.
- **Continued advancement of small molecule TREM2 agonist program toward the clinic:** 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. 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. The Company expects to submit an Investigational New Drug (IND) application to the FDA and, subject to FDA clearance of the IND, initiate clinical development for its lead small molecule TREM2 agonist, with an initial focus in genetically defined Alzheimer's disease subpopulations, in the fourth quarter of 2023.

Corporate

- **Added distinguished leader in biopharmaceutical industry to Board of Directors:** In May 2023, Vigil appointed Samantha Budd Haerberlein, Ph.D. to its Board of Directors. Dr. Budd Haerberlein brings more than 20 years of biopharmaceutical industry experience across research, translational medicine, and clinical development with a focus on CNS indications, including rare and common neurological disorders.

Upcoming Events

Vigil plans to participate at the following investor conferences:

- Mizuho Neuroscience Summit on May 16, 2023
- Jefferies Healthcare Conference from June 7-9, 2023

First Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities were \$164.5 million as of March 31, 2023, compared to \$186.6 million as of December 31, 2022. 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 first quarter ended March 31, 2023, were \$13.8 million, compared to \$10.4 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 advancing the VGL101 program into a phase 2 clinical trial, and increased headcount to support the Company's continued growth.
- **General and Administrative (G&A) Expenses:** G&A expenses for the first quarter ended March 31, 2023, were \$6.9 million, compared to \$5.0 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 first quarter ended March 31, 2023, were \$19.8 million, compared to \$15.3 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 candidate, is a fully human monoclonal antibody agonist targeting human triggering receptor expressed on myeloid cells 2 (TREM2) and is in a Phase 2 proof-of-concept trial in patients with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP), a rare and fatal neurodegenerative disease. We are also conducting IND-enabling studies with a novel small molecule TREM2 agonist program 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 and focus; the potential design, access, benefits and success of *ALSPAware*, including the belief that the program will ease the diagnostic journey for patients and their families; 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 in the fourth quarter of 2023, filing an IND application for its small molecule TREM2 agonist program and the initiation of the Phase 1 clinical trial in the fourth quarter of 2023 and reporting full data analysis from its Phase 1 healthy volunteer trial of VGL101 in the second half of 2023; the success and timing of its interactions with regulatory authorities; expectations regarding the development of VGL101 in ALSP and other indications, its small molecule TREM2 agonist program in AD, and the development of other pipeline candidates, including its expected therapeutic benefits as well as its safety and tolerability profile; the Company’s cash runway into first quarter of 2025; expectations regarding the use of capital, expenses and other financial results in the future. 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 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; uncertainties associated with the impact of the COVID-19 pandemic on its business and operations; as well as the risks and uncertainties identified in the Company’s filings with the Securities and Exchange Commission (SEC), including Vigil’s Annual Report on Form 10-K for the year ended December 31, 2022 and in any subsequent filings it may make 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	
	March 31, 2023	March 31, 2022
Operating expenses:		
Research and development	\$ 13,834	\$ 10,365
General and administrative	6,941	4,967
Total operating expenses	<u>20,775</u>	<u>15,332</u>
Loss from operations	<u>(20,775)</u>	<u>(15,332)</u>
Other income (expense):		
Interest income, net	985	2
Other income (expense), net	(5)	(4)
Total other expense, net	<u>(980)</u>	<u>(2)</u>
Net loss and comprehensive loss	<u>\$ (19,795)</u>	<u>\$ (15,334)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.51)</u>	<u>\$ (0.58)</u>
Weighted—average common shares outstanding, basic, and diluted	<u>38,546,012</u>	<u>26,660,246</u>

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

	March 31, 2023	December 31, 2022
Cash, cash equivalents, and marketable securities	\$ 164,480	\$ 186,605
Total assets	192,361	200,393
Total liabilities	21,021	11,312
Total stockholders' equity	171,340	189,081

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