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): August 8, 2022

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.
1 Broadway, 7th Floor, Suite 07-300
Cambridge, Massachusetts, 02142
(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 August 8, 2022, Vigil Neuroscience, Inc. issued a press release announcing its financial results for the three and six months ended June 30, 2022 (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 August 8, 2022
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: August 8, 2022

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

Exhibit 99.1

Vigil Neuroscience Reports Second Quarter 2022 Financial Results and Provides Business Update

– Initiated a Phase 1 trial of VGL101 in healthy volunteers in Australia –

– Received U.S. FDA orphan drug designation for VGL101 for the treatment of patients with ALSP –

– Prioritizing VGL101 in ALSP and small molecule TREM2 agonist programs; cash runway now extended through the end of the second quarter of 2024 –

– On track to report top line data from the VGL101 Phase 1 trial in healthy volunteers and initiate the Phase 2 trial in ALSP patients in the fourth quarter of 2022 –

– Further strengthened Board of Directors with appointment of Suzanne Bruhn, Ph.D.–

CAMBRIDGE, Mass., August 8, 2022 (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, 2022 and provided an update on recent progress.

"We continue to make significant progress in our VGL101 program, including the initiation of our Phase 1 study in healthy volunteers in Australia. In addition, the FDA recently granted VGL101 orphan drug designation for the treatment of ALSP supporting the significant unmet need of ALSP patients. We remain on track to report VGL101 Phase 1 topline data and to initiate a Phase 2 proof-of-concept trial for VGL101 in ALSP in the fourth quarter of 2022," said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. "We are also excited about the progress we've made with our first-in-class small molecule TREM2 agonist program. We continue to advance our IND-enabling work and plan to move our small molecule program into the clinic next year."

Dr. Magovčević-Liebisch continued, "As part of the continuous evaluation of our programs we have elected to prioritize VGL101 in ALSP and our small molecule TREM2 agonist programs, which will extend our cash runway and also better position us to continue advancing these potentially transformative treatments for patients with both rare and common neurodegenerative diseases."

Recent Highlights and Anticipated Milestones

VGL101, Monoclonal Antibody TREM2 Agonist

- **The Company remains on track to report VGL101 Phase 1 healthy volunteer topline data and initiate a Phase 2 proof-of-concept trial in adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP) patients in the fourth quarter of 2022:** Vigil recently completed dosing of the 20 mg/kg multiple ascending dose cohort without any safety signals in its U.S. Phase 1 trial of VGL101 in healthy volunteers. The Company also initiated dosing of VGL101 at 30 mg/kg in its Phase 1 trial in healthy volunteers in Australia in an effort to maintain optionality to support patients with rare and common neurodegenerative diseases beyond ALSP.

- **VGL101 received U.S. Food and Drug Administration (FDA) orphan drug designation:** In July, the FDA granted orphan drug designation to VGL101 for the treatment of patients with ALSP. The FDA's Orphan Drug Designation program provides orphan designation to drugs and biologics that are intended to treat, diagnose or prevent rare diseases affecting fewer than 200,000 people in the U.S. This designation provides the potential to obtain certain benefits, including financial incentives to support clinical development and seven years of marketing exclusivity upon FDA approval.
- **Vigil presented key findings demonstrating the high frequency of initial misdiagnosis of ALSP at the 8th Congress of the European Academy of Neurology (EAN):** Vigil presented a poster entitled, "Adult-Onset Leukoencephalopathy with Axonal Spheroids and Pigmented Glia (ALSP): Initial Misdiagnosis," at EAN highlighting the frequency of initial misdiagnosis of ALSP through a comprehensive, systematic literature review. The findings of this systematic review demonstrated a high incidence of initial misdiagnosis of ALSP and confirmed the need for early, accurate diagnosis to allow rapid therapeutic intervention for potential cessation or slowing of the progression of this devastating disorder and improvement of survival time. This poster can be accessed on the Publications page of the Company's website.
- **Vigil presented two posters at the Alzheimer's Association International Conference (AAIC) further supporting the evaluation of VGL101 as a potential therapeutic for ALSP:** Vigil presented a poster entitled, "VGL101 Rescues CSF1R Dysfunction in Human Microglia and Macrophages: Evaluation of *In Vitro* TREM2 Agonism in Models of a CSF1R-dependent Leukodystrophy," demonstrating that TREM2 agonism by VGL101 was able to compensate for CSF1R dysfunction in *in vitro* ALSP models utilizing healthy, human monocyte derived macrophages (hMDM) and induced pluripotent stem cell derived human microglia (iMGL). Vigil also presented a poster entitled, "Phenotypic Features of Adult-Onset Leukoencephalopathy with Axonal Spheroids and Pigmented Glia (ALSP): Presenting Symptoms and Clinical Course," summarizing its systematic literature review of published case studies on the clinical and genetic features of ALSP to better understand the phenotypic characteristics of ALSP. Data from a cohort of 292 patients, representing the largest case series to date of ALSP, confirmed and expanded the previous, smaller case reports on the phenotypic characteristics of ALSP. These posters can be accessed on the Publications page of the Company's website.

Small Molecule TREM2 Agonist Program

- **IND-enabling studies in small molecule TREM2 agonist program are progressing**: The Company's first-in-class, orally available and highly CNS penetrant small molecule program is designed to activate TREM2 for the treatment of common neurodegenerative diseases. Vigil has established that its small molecules have a different mechanism of action and bind to a different location than VGL101, providing the potential for additional optionality in positioning these molecules in different patient populations and potential differentiation from TREM2 antibody therapeutics. Based on these findings, the Company no longer believes that the originally planned Phase 1b biomarker trial of VGL101 will inform clinical development of the small molecule in Alzheimer's Disease (AD) and is no longer planning to conduct this biomarker trial. The Company continues to expect to file an Investigational New Drug (IND) application with an initial focus in genetically defined AD subpopulations in 2023.

Corporate

- **Prioritization of development studies extends cash runway:** Vigil has elected to prioritize VGL101 in ALSP and its small molecule TREM2 agonist programs. The Company no longer plans to conduct the Phase 1b biomarker trial of VGL101 in AD and plans to defer the initiation of the planned Phase 2 clinical trial of VGL101 for the treatment of cerebral adrenoleukodystrophy (cALD). This strategic prioritization is expected to extend the Company's cash runway through the end of the second quarter of 2024.
- **Further strengthened Board of Directors:** Vigil recently appointed Suzanne Bruhn, Ph.D. to its Board of Directors. Dr. Bruhn brings over 20 years of executive leadership experience in the biopharmaceutical industry with deep operational and global regulatory experience. In addition, her extensive knowledge of the rare disease and neuroscience space and proven track record of developing and commercializing therapies for serious diseases will be invaluable as the Company advances the clinical development of its pipeline candidates.

Second Quarter 2022 Financial Results

- **Cash Position:** Cash and cash equivalents were $148.9 million as of June 30, 2022. The Company expects its cash and cash equivalents to fund its operational plans through the end of the second quarter of 2024.
- **R&D Expenses:** Research and development expenses for the second quarter ended June 30, 2022, were $12.1 million, compared to $8.6 million for the same period in 2021. The increase was primarily attributable to the continued advancement of our pipeline programs and increases in headcount to support our continued growth.
- **G&A Expenses:** General and administrative expenses for the second quarter ended June 30, 2022, were $4.9 million, compared to $2.1 million for the same period in 2021. The increase was primarily attributable to increases in headcount-related costs and professional service fees associated with operating as a public company.
- **Net Loss:** Loss from operations for the second quarter ended June 30, 2022, were $17.0 million, compared to $11.4 million for the same period in 2021. The increase was primarily attributable to higher operating costs in the current period to support the advancement of the Company's pipeline as well as increased costs associated with operating as a public company.

About Vigil Neuroscience

Vigil Neuroscience is a microglia-focused therapeutics 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.

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 progress and timing of the preclinical and clinical development of Vigil's programs, including the availability of data and expected timing for reporting data from the VGL101 Phase 1 trial, the initiation of its Phase 2 proof-of-concept trial in the fourth quarter of 2022 and the filing of an IND application for its small molecule TREM2 agonist program in 2023; expectations regarding the development of VGL101 in ALSP and other indications; expectations regarding the development of its small molecule TREM2 agonist program in Alzheimer's disease (AD); expectations regarding the development of other pipeline candidates; the anticipated contribution of the members of the Company's board of directors and executives to its operations and progress; and the extension of the Company's cash runway as a result of the prioritization of its programs, expectations regarding the use of capital, expenses and other financial results in 2022 and 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 and its ability to work with the FDA to successfully remove the partial clinical hold; 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 IPO registration statement, its Annual Report on Form 10-K for the year ended December 31, 2021, its Quarterly Report on Form 10-Q for the three months ended March 31, 2022 and in any subsequent filings it may make with the SEC, including its Quarterly Report on Form 10-Q for the three months ended June 30, 2022. 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, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Operating expenses:				
Research and development	$ 12,097	$ 8,648	$ 22,462	$ 15,401
General and administrative	4,945	2,128	9,912	3,293
Total operating expenses	17,042	10,776	32,374	18,694
Loss from operations	(17,042)	(10,776)	(32,374)	(18,694)
Other income (expense):				
Change in fair value of the related party antidilution obligation	—	(584)	—	(836)
Change in fair value of Series A preferred stock tranche obligation	—	(7)	—	(28)
Interest income, net	32	1	34	3
Other income (expense), net	(5)	(1)	(9)	(3)
Total other expense, net	27	(591)	25	(864)
Net loss and comprehensive loss	$ (17,015)	$ (11,367)	$ (32,349)	$ (19,558)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.60)	$ (7.48)	$ (1.18)	$ (12.96)
Weighted—average common shares outstanding, basic and diluted	28,150,051	1,518,999	27,409,264	1,509,474

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

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 148,912	$ 91,420
Total assets	157,928	102,441
Total liabilities	7,302	9,945
Total stockholders' equity (deficit)	150,626	(69,443)

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