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 10, 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 November 10, 2022, Vigil Neuroscience, Inc. issued a press release announcing its financial results for the three and nine months ended September 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 November 10, 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: November 10, 2022

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

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

– Announced interim topline data from Phase 1 trial of VGL101 in healthy volunteers–

– On track to initiate Phase 2 proof-of-concept trial in ALSP patients this quarter –

– Received Fast Track designation from the FDA for VGL101 in patients with ALSP –

– Completed $75 million PIPE from new and existing investors, extending cash runway into the first quarter of 2025 –

CAMBRIDGE, Mass., November 10, 2022 — 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, 2022 and provided an update on recent progress.

"We have continued to make substantial progress on our VGL101 program in recent months evidenced by encouraging interim topline data from our ongoing Phase 1 healthy volunteer trial. We believe the excellent overall clinical profile seen to date with repeat dosing of VGL101 at 20 mg/kg supports the therapeutic potential of VGL101 in ALSP patients and we are on to track to initiate a Phase 2 trial with a 20 mg/kg dose this quarter," said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. "In addition, the FDA recently granted Fast Track designation for VGL101 in patients with ALSP, further acknowledging the significant unmet need of these patients for which there are no currently approved therapies."

Dr. Magovčević-Liebisch continued, "We are also very pleased to have gained support from new and existing investors through a $75 million financing, allowing us to continue advancing our potentially transformative treatments, including VGL101 and our small molecule TREM2 agonist program, for both rare and common neurodegenerative diseases."

Recent Highlights and Anticipated Milestones

VGL101, Monoclonal Antibody TREM2 Agonist

- **The Company announced interim topline data from its ongoing VGL101 Phase 1 healthy volunteer trial:** On November 2, 2022, Vigil reported interim topline data from its ongoing VGL101 Phase 1 trial. This trial is designed to evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of VGL101 in healthy volunteers. As of October 7, 2022, the trial had enrolled 82 healthy volunteers who received either VGL101 (n=68) at doses of 1, 3, 10, 20, 30 or 40 mg/kg or placebo (n=14). Based on these data, VGL101 was found to be safe and well-tolerated at doses up to 40 mg/kg SAD and 20 mg/kg MAD. VGL101 showed a linear, predictable PK profile at all doses and a half-life that supports monthly IV dosing. Importantly, VGL101 achieved dose dependent, durable decreases in levels of sTREM2 in the cerebrospinal fluid (CSF) demonstrating proof of target engagement. VGL101 20 mg/kg repeat dosing was

associated with robust reduction in sTREM2 levels and decreases were still observed 28 days after the third and final dose. VGL101 is the first antibody reported to demonstrate durability of TREM2 engagement in a clinical setting. VGL101 also showed durable increases in sCSF1R levels in the CSF after repeat dosing. The Company continues to dose escalate in its Phase 1 trial in healthy volunteers to maintain optionality to support patients across all potential indications and has been cleared to initiate a 60 mg/kg cohort in Australia. The Company expects to provide the final data analysis from the Phase 1 trial at a future medical conference.

- **Vigil remains on track to initiate a Phase 2 proof-of-concept trial in ALSP patients this quarter**: The Company believes that the interim dataset from the Phase 1 trial of VGL101 supports the initiation of a Phase 2 proof-of-concept trial in patients with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP) with a 20 mg/kg dose and is on track to begin dosing patients in the Phase 2 trial this quarter.
- **The Company received Fast Track designation from the FDA for VGL101**: Vigil announced it received Fast Track designation from the U.S. Food and Drug Administration (FDA) for VGL101 for the treatment of patients with ALSP. The benefits of Fast Track designation may include early and frequent communications with the FDA as well as the potential for priority review and a rolling submission of the marketing application. In July 2022, the Company announced that the FDA also granted orphan drug designation to VGL101 for the treatment of patients with ALSP.

Small Molecule TREM2 Agonist Program

- **IND-enabling studies in small molecule TREM2 agonist program are progressing as planned**: 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. The Company continues to expect to file an Investigational New Drug (IND) application with an initial focus in genetically defined Alzheimer's disease subpopulations in 2023.

Corporate

- **Completed $75 Million Private Placement Financing:** The Company completed a private investment in public equity (PIPE) financing with gross proceeds of approximately $75.0 million, which included participation from new and existing investors. The financing extends the Company's runway into the first quarter of 2025.

Upcoming Events

- Vigil plans to participate in a fireside chat at the following investor conferences:
  - Guggenheim 4th Annual Immunology and Neurology Day scheduled for November 14, 2022, at 1:35 p.m. ET.
  - Stifel 2022 Healthcare Conference scheduled for November 15, 2022, at 8:35 a.m. ET.

- Jefferies London Healthcare Conference scheduled for November 16, 2022, at 2:05 p.m. GMT.

- On December 6, 2022, Vigil plans to host an in-person ALSP Key Opinion Leader (KOL) event for the investment community in New York City to provide further details on the ALSP disease background, epidemiology and patient journey. In addition, the Company plans to present the Phase 2 trial design and objectives as well as interim MRI findings from the ongoing natural history study. A live webcast of this event will also be available on the Company's website.

Third Quarter 2022 Financial Results

- **Cash Position:** Cash and cash equivalents were $203.9 million as of September 30, 2022. The Company expects its cash and cash equivalents to fund its operational plans into the first quarter of 2025.

- **R&D Expenses:** Research and development expenses for the third quarter ended September 30, 2022, were $12.8 million, compared to $7.8 million for the same period in 2021. The increase was primarily attributable to the continued advancement of the VGL101 program, with increased clinical trial related expenses as the program entered Phase 1 clinical trials in the fourth quarter of 2021, preclinical studies related to our small molecule program, and increases in headcount to support our continued growth.

- **G&A Expenses:** General and administrative expenses for the third quarter ended September 30, 2022, were $4.8 million, compared to $2.9 million for the same period in 2021. The increase was primarily attributable to increases in headcount-related costs and other operating costs associated with operating as a public company.

- **Net Loss:** Loss from operations for the third quarter ended September 30, 2022, were $17.5 million, compared to $10.7 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.

About Vigil Neuroscience

Vigil Neuroscience is a clinical-stage, 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 belief that Fast Track designation recognizes the significant unmet need of ALSP patients and the therapeutic potential of VGL101; beliefs about the opportunity for early and frequent communications with the FDA as well as the potential for priority review and a rolling submission of the marketing application; beliefs about the profile of VGL101, including as to its safety and tolerability; the extension of the Company's cash runway into first quarter of 2025 as a result of the PIPE investment, 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 conducting and reporting data analyses; 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 and early interim data will be predictive of the results of later preclinical studies and data readouts, and other 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 quarter ended June 30, 2022 and in any subsequent filings it may make with the SEC, including its Quarterly Report on Form 10-Q for the quarter ended September 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		Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
Operating expenses:				
Research and development	$ 12,791	$ 7,810	$ 35,253	$ 23,211
General and administrative	4,846	2,928	14,758	6,221
Total operating expenses	17,637	10,738	50,011	29,432
Loss from operations	(17,637)	(10,738)	(50,011)	(29,432)
Other income (expense):				
Change in fair value of the related party antidilution obligation	—	—	—	(836)
Change in fair value of Series A preferred stock tranche obligation	—	—	—	(28)
Interest income, net	163	—	197	3
Other income (expense), net	(26)	(2)	(35)	(5)
Total other expense, net	137	(2)	162	(866)
Net loss and comprehensive loss	$ (17,500)	$ (10,740)	$ (49,849)	$ (30,298)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.53)	$ (6.98)	$ (1.70)	$ (19.94)
Weighted—average common shares outstanding, basic and diluted	33,303,345	1,539,769	29,395,548	1,519,686

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

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 203,863	$ 91,420
Total assets	215,509	102,441
Total liabilities	9,597	9,945
Total stockholders' equity (deficit)	205,912	(69,443)

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