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): July 24, 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 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 7.01 Regulation FD Disclosure.

On July 24 2024, Vigil Neuroscience, Inc. (the "Company") issued a press release announcing interim data from its ongoing Phase 1 clinical trial evaluating VG-3927 in healthy volunteers. A copy of the press release is furnished herewith as Exhibit 99.1.

The information set forth under Item 7.01 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 8.01 Other Events.

On July 24, 2024, the Company announced interim data from its ongoing Phase 1 clinical trial evaluating VG-3927 in healthy volunteers – the announcement included the following information:

As of June 30, 2024, the trial had enrolled 80 healthy volunteers, of which 60 have received VG-3927 across single ascending dose (SAD) and multiple ascending dose (MAD) cohorts.

- Safety and tolerability profile observed in individual doses in six SAD and two MAD cohorts in the ongoing Phase 1 clinical trial supports continued clinical development of VG-3927.
- All adverse events (AEs) were mild or moderate in severity, and all AEs resolved without intervention. No serious adverse events have been reported to date.
- VG-3927 demonstrated a predictable PK profile that is supportive of once-daily dosing.
- In the SAD and MAD cohorts, VG-3927 achieved a robust and sustained decrease of sTREM2 in the CSF.
- VG-3927 also showed an increase in osteopontin/secreted phosphoprotein 1 (SPP1), a biomarker associated with neuroprotective microglia, after repeat dosing.
- An effect on soluble Colony Stimulating Factor 1 Receptor (sCSF1R), a microglial trophic factor, has not been observed to date.

As part of the Phase 1 clinical trial, the Company has commenced screening for a cohort of Alzheimer's disease (AD) patients, including some participants who carry TREM2 or other disease-related variants to explore the biomarker response of VG-3927 after a single dose. The Company plans to use these data to inform the development strategy for subsequent and larger trials evaluating VG-3927 in AD. The Company plans to report the complete Phase 1 clinical data in the first quarter of 2025.

Forward-Looking Statements

The disclosure under this Item 8.01 contains "forward-looking statements" of 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 therapeutic benefit of our product candidates, including VG-3927, and the expected therapeutic benefits of such programs; the timing and availability of future interim data readouts as well as the complete clinical data from VG-3927's Phase 1 clinical trial; VG-3927's potential as a TREM2 agonist and the clinical trial enrollment. Forward-looking statements are based on the Company'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; 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 interactions with the FDA – including the Company's discussions regarding the partial clinical hold on VG-3927; 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 March 31, 2024 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. All disclosure under this Item 8.01 is as of the date of this Form 8-K, and the Company undertakes no duty to update this information unless required by law.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release of Vigil Neuroscience, Inc., dated July 24, 2024.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded in 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: July 24, 2024

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

Vigil Neuroscience Announces Interim Data from its Ongoing Phase 1 Clinical Trial Evaluating VG-3927 in Healthy Volunteers Supporting Continued Development in Alzheimer's Disease

- Safety, tolerability, pharmacokinetic and pharmacodynamic profile of VG-3927 supports continued development as potential once-daily oral therapy for Alzheimer's disease (AD) -

- VG-3927 achieved robust decrease of sTREM2 in CSF demonstrating clinical proof-of-target engagement-

- New preclinical and clinical data from SAD cohorts to be presented at upcoming 2024 Alzheimer's Association International Conference (AAIC) -

- Company plans to report complete Phase 1 data, including data from AD cohort, in Q1'2025 -

WATERTOWN, Mass., July 24, 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 interim data from its ongoing Phase 1 clinical trial of VG-3927 in healthy volunteers. Collectively, the interim safety, tolerability, pharmacokinetic (PK) and pharmacodynamic (PD) profile supports continued clinical development of VG-3927 as a potential once-daily oral therapy for AD. Additionally, these data showed that VG-3927 demonstrated functional and durable target engagement.

"We are encouraged by these data which demonstrate that VG-3927 has the potential to become a differentiated approach to treating AD," said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. "With approximately 6.7 million Americans living with AD, there is a critical need for new therapies with improved safety and efficacy that can broadly address multiple aspects of AD disease pathophysiology."

"These interim clinical findings showed that VG-3927 had a significant impact on sTREM2, a key biomarker in AD, and supports VG-3927 as a potent molecule that functionally engages TREM2 receptors in the brain. We achieved similar levels of sTREM2 target engagement with our monoclonal antibody iluzanebart in its Phase 1 clinical trial. These data further strengthen our belief that VG-3927 is acting as a TREM2 agonist and converting microglia into a neuroprotective state," said Petra Kaufmann, M.D., F.A.A.N., Chief Medical Officer of Vigil. "Combined with the extensive preclinical data that we have collected, we believe VG-3927 is well-positioned for further development in AD. We look forward to advancing VG-3927 with the goal of ultimately providing a new therapy to those impacted by AD."

The ongoing trial is a Phase 1 single and multiple ascending dose trial to assess the safety, tolerability, PK and PD of VG-3927. As of June 30, 2024, the trial had enrolled 80 healthy volunteers, of which 60 have received VG-3927 across multiple SAD and MAD cohorts.

Key takeaways from the interim data include the following:

- Safety and tolerability profile observed in individual doses in six SAD and two MAD cohorts in the ongoing Phase 1 clinical trial supports continued clinical development of VG-3927.
- All adverse events (AEs) were mild or moderate in severity, and all AEs resolved without intervention. No serious adverse events have been reported to date.
- VG-3927 demonstrated a predictable PK profile that is supportive of once-daily dosing.
- In the SAD and MAD cohorts, VG-3927 achieved a robust and sustained decrease of sTREM2 in the CSF.
- VG-3927 also showed an increase in osteopontin/secreted phosphoprotein 1 (SPP1), a biomarker associated with neuroprotective microglia, after repeat dosing.
- An effect on soluble Colony Stimulating Factor 1 Receptor (sCSF1R), a microglial trophic factor, has not been observed to date.

As part of the Phase 1 clinical trial, the Company has commenced screening for a cohort of AD patients, including some participants who carry TREM2 or other disease-related variants to explore the biomarker response of VG-3927 after a single dose. The Company plans to use these data to inform the development strategy for subsequent and larger trials evaluating VG-3927 in AD. Vigil plans to report the complete Phase 1 clinical data, including data from the AD patient cohort, in the first quarter of 2025.

The Company also announced today that it plans to present new preclinical data from its small molecule program, including *in vivo* AD-related functional data, and clinical data from the VG-3927 SAD cohorts in the Phase 1 clinical trial, in an oral presentation at the upcoming 2024 Alzheimer's Association International Conference (AAIC) taking place on July 28 – August 1, 2024 in Philadelphia, Pennsylvania and virtually. Please click here for more information on Vigil's presentations at AAIC.

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) patients, including some who carry TREM2 and other disease-associated variants.

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: Vigil's

strategy, business plans and focus; the potential therapeutic benefit of our product candidates, including VG-3927, and the expected therapeutic benefits of such programs as well as the potential market size and ability to address a major unmet medical need; the timing and availability of future interim data readouts as well as the complete Phase 1 clinical data from VG-3927's Phase 1 clinical trial; VG-3927's potential as a TREM2 agonist and its ability to convert microglia into a neuroprotective state. 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; 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 interactions with the FDA – including the Company's discussions regarding the partial clinical hold on VG-3927; 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 March 31, 2024 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.

Investor Contact:

Leah Gibson
Vice President, Investor Relations & Corporate Communications
Vigil Neuroscience, Inc.
lgibson@vigilneuro.com

Media Contact:

Megan McGrath
CTD Comms, LLC
megan@ctdcomms.com