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): September 17, 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 September 17, 2024, Vigil Neuroscience, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has removed the partial clinical hold on its ongoing Phase 1 clinical trial of VG-3927. 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 September 17, 2024, the Company announced that the FDA has removed the partial clinical hold on its ongoing Phase 1 clinical trial of VG-3927. The FDA's decision was based on a complete response submitted by the Company.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release of Vigil Neuroscience, Inc., dated September 17, 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: September 17, 2024

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

Vigil Neuroscience Announces FDA Has Removed Partial Clinical Hold on VG-3927

WATERTOWN, Mass. – September 17, 2024 – 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 that the U.S. Food and Drug Administration (FDA) has removed the partial clinical hold on its ongoing Phase 1 clinical trial of VG-3927. The FDA's decision was based on a complete response submitted by the Company.

"We are pleased with the resolution of the partial clinical hold – a decision that was supported by non-clinical and clinical data from our ongoing Phase 1 trial," said Petra Kaufmann, M.D., F.A.A.N., Chief Medical Officer at Vigil. "While the partial clinical hold did not delay clinical development of VG-3927, the option to increase the exposure limit provides us the best opportunity to explore the full pharmacology of VG-3927 as a potentially novel, next generation therapy for those living with Alzheimer's disease."

In July 2024, the Company reported interim data from the ongoing Phase 1 single- and multiple-ascending dose clinical trial evaluating VG-3927 in healthy volunteers. These data showed that the safety and tolerability profile observed in individual doses in six SAD and two MAD cohorts supported continued clinical development of VG-3927. In addition, VG-3927 demonstrated a predictable PK profile supportive of once-daily dosing. Importantly, VG-3927 achieved a robust and sustained decrease of soluble TREM2 in the CSF demonstrating clinical proof-of-target engagement. VG-3927 also showed an increase in osteopontin/secreted phosphoprotein 1 (SPP1) after repeat dosing.

As part of the Phase 1 clinical trial, the Company has initiated dosing of a cohort of Alzheimer's disease patients, including some participants who carry TREM2 or other disease-related variants to explore the biomarker response of VG-3927 after a single dose. Vigil expects 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, including data from the AD patient cohort, in the first quarter of 2025.

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; the timing, availability and utility of the complete Phase 1 clinical data from VG-3927's Phase 1 clinical trial, and Vigil's plans for further evaluation of the pharmacology of VG-3927. 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 clinical trials; whether results from preclinical studies and clinical trials will be predictive of the results of later preclinical studies and clinical trials; whether interim data results and analysis will be predictive of complete data results and analysis; 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 June 30, 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.

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