

**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 8, 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 Road, 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<br>Symbol(s) | Name of each exchange<br>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 8, 2023, Vigil Neuroscience, Inc. (the “Company”) issued a press release announcing an update on its Small Molecule TREM2 Agonist Program (the “Press Release”). 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.**

The Company received notification from the U.S. Food and Drug Administration (FDA) regarding its Investigational New Drug (IND) application to evaluate the Company’s oral small molecule TREM2 agonist VG-3927. The IND for VG-3927 is now open and the Company’s Phase 1 clinical trial in healthy volunteers is allowed to proceed with a partial clinical hold related to maximum exposure limit. At this time, the Company does not anticipate any delay in the current clinical development plans for VG-3927 and expects to commence dosing of the Phase 1 trial evaluating VG-3927 in healthy volunteers in October 2023. Per the notification, the FDA has limited the maximum exposure of VG-3927 in healthy volunteers in the planned Phase 1 clinical trial. Based on preclinical studies, the Company believes that the maximum exposure limit exceeds the predicted efficacious dose of VG-3927. From the initial comments received from the FDA, the Company believes that the partial clinical hold was not a result of any preclinical toxicology findings or TREM2 pharmacology. The Company expects to receive additional details from the FDA within the next 30 days and will work closely with the FDA to address the partial clinical hold.

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 timing for the commencement and dosing of patients in VG-3927’s Phase I trial; anticipated impact of the partial clinical hold on the Company’s clinical development plans; regulatory progress, clinical progress and clinical development plans for VG-3927; and expectations regarding the timing of additional regulatory information from the FDA. 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 risks and uncertainties related to the initiation and completion of clinical trials; Company’s ability to commence and recruit study subjects for clinical trials; the availability and timing of results and data from clinical trials; the timing and content of additional regulatory information from the FDA; the Company’s ability to work with the FDA to successfully remove 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 June 30, 2023 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. 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.

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**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| <b>Exhibit<br/>No.</b> | <b>Description</b>  |
|------------------------|---|
| 99.1                   | <a href="#">Press release dated September 8, 2023</a>                       |
| 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: September 8, 2023

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



**Vigil Neuroscience Announces Update on its Small Molecule  
TREM2 Agonist Program**

*- Announced VG-3927 as lead candidate to enter clinical development for potential treatment of Alzheimer's Disease -*

*- IND for VG-3927 now open; Phase 1 clinical trial in healthy volunteers allowed to proceed with partial clinical hold related to maximum exposure limit –*

*- Phase 1 dosing expected to commence in October 2023; No anticipated delays in current clinical development plans -*

*- Company to host virtual R&D event highlighting its small molecule TREM2 agonist program on September 13, 2023 -*

**WATERTOWN, Mass., September 8, 2023 (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 that it has received notification from the U.S. Food and Drug Administration (FDA) regarding its Investigational New Drug (IND) application to evaluate the Company's oral small molecule TREM2 agonist VG-3927. The IND for VG-3927 is now open and the Company's Phase 1 clinical trial in healthy volunteers is allowed to proceed with a partial clinical hold related to maximum exposure limit. At this time, the Company does not anticipate any delay in the current clinical development plans for VG-3927 and expects to commence dosing of the Phase 1 trial evaluating VG-3927 in healthy volunteers in October 2023.

Per the notification, the FDA has limited the maximum exposure of VG-3927 in healthy volunteers in the planned Phase 1 clinical trial. Based on preclinical studies, the Company believes that the maximum exposure limit exceeds the predicted efficacious dose of VG-3927. From the initial comments received from the FDA, the Company believes that the partial clinical hold was not a result of any preclinical toxicology findings or TREM2 pharmacology. The Company expects to receive additional details from the FDA within the next 30 days and will work closely with the FDA to address the partial clinical hold.

The Company also announced today that it will host a virtual R&D event highlighting its small molecule TREM2 agonist program for AD on Wednesday, September 13, 2023, from 7:30 a.m. to 9:00 a.m. ET.

The event will highlight new preclinical data for VG-3927, discuss current treatment approaches for AD, and Vigil's TREM2-focused clinical approach for treating AD guided by its precision medicine strategy. Vigil's management team will be joined by:

- Marco Colonna, M.D., Robert Rock Belliveau Professor of Pathology & Immunology, Washington University School of Medicine. Vigil Neuroscience Scientific Advisory Board Chairman; and,
- Samuel E. Gandy, Ph.D., M.D., Mount Sinai Professor of Alzheimer's Disease Research, Professor of Neurology & Psychiatry and Associate Director of Mount Sinai Alzheimer's Disease Research Center. Past Chairman, National Medical & Scientific Advisory Council of the Alzheimer's Association.

To access the live webcast of this event, please [register here](#) or visit "[Events & Presentations](#)" in the "Investors" section of the Vigil website at [www.vigilneuro.com](http://www.vigilneuro.com). An archived replay will be available for approximately 90 days following the presentation.

### **About VG-3927**

Vigil's highly active, selective, and brain-penetrant small molecule TREM2 agonist, VG-3927, is designed to act as a molecular glue that potentiates the TREM2 signaling response to natural damage ligands. In preclinical studies, Vigil has established that VG-3927 demonstrated on-target TREM2 activation across both common and rare TREM2 variants. Additionally, VG-3927 demonstrated preclinically that it was able to deliver *in vivo* TREM2 responses within the central nervous system at a magnitude and specificity similar to VGL101.

### **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 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. We are 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) in genetically defined subpopulations.

### **Forward-Looking Statements**

This press release includes certain disclosures that contain "forward-looking statements" of Vigil Neuroscience, Inc.'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 timing for the commencement and dosing of patients in VG-3927's Phase I trial; anticipated impact of the partial clinical hold on the Company's clinical development plans; regulatory progress, clinical progress and clinical development plans for VG-3927; and expectations regarding the timing of additional regulatory information from the U.S. Food and Drug Administration ("FDA"). 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 risks and uncertainties related to the initiation and completion of clinical trials; Company's ability to commence and recruit study subjects for clinical trials; the availability and timing of results and data from clinical trials; the timing and content of

additional regulatory information from the FDA; the Company's ability to work with the FDA to successfully remove 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 June 30, 2023 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.

**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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