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): March 30, 2023

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 March 30, 2023, Vigil Neuroscience, Inc. (the "Company"), issued a press release titled "Vigil Neuroscience Announces FDA Has Lifted the Partial Clinical Hold on VGL101".

The information under this Item 7.01, including Exhibit 99.1 hereto, is being furnished herewith and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On March 30, 2023, the Company announced that the U.S. Food and Drug Administration had lifted its partial clinical hold on doses greater than 20 mg/kg for VGL101 in its ongoing and future clinical trials in patients with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia ("ALSP"). VGL101, the Company's lead product candidate, is currently being studied in IGNITE, a Phase 2 proof-of-concept trial in patients with ALSP as well as in an ongoing Phase 1 single and multiple ascending dose healthy volunteer trial.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated March 30, 2023 (furnished herewith)
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: March 30, 2023

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

Exhibit 99.1

Vigil Neuroscience Announces FDA Has Lifted the Partial Clinical Hold on VGL101

- *Company remains on track to report interim data from Phase 2 trial in the second half of 2023 -*

WATERTOWN, Mass., March 30, 2023 — 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 lifted its partial clinical hold on doses greater than 20 mg/kg for VGL101 in its ongoing and future clinical trials in patients with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP). VGL101, Vigil's lead product candidate, is currently being studied in IGNITE, a Phase 2 proof-of-concept trial in patients with ALSP as well as in an ongoing Phase 1 single and multiple ascending dose (SAD and MAD) healthy volunteer trial.

"We are happy to share that the FDA has lifted the partial clinical hold on VGL101 based on supporting clinical data from our ongoing Phase 1 trial," said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. "Although we believe that 20 mg/kg is a clinically relevant dose in ALSP, we are very pleased that the hold has been lifted as we believe it's important to maintain optionality to develop treatments that support patients suffering from both rare and common neurodegenerative indications."

In November 2022, Vigil reported interim top-line data from the Phase 1 trial in healthy volunteers in the United States and Australia. Based on these data, VGL101 demonstrated favorable safety and tolerability profiles at doses up to 40 mg/kg SAD and 20 mg/kg MAD. The Company expects to report the full data analysis up to 60 mg/kg from the Phase 1 trial in the second half of 2023.

In December 2022, Vigil initiated a Phase 2 proof-of-concept clinical trial evaluating VGL101 in patients with ALSP. IGNITE, the first interventional trial in ALSP, is a global Phase 2, open-label trial designed to evaluate the safety and tolerability of VGL101 in up to 15 patients with symptomatic ALSP who have a *CSF1R* gene mutation. Patients enrolled in the trial will receive an intravenous (IV) infusion of 20 mg/kg of VGL101 approximately every 4 weeks for a treatment duration of one year. The Company expects to report six-month interim data from the first six patients in this trial in the second half of 2023.

The FDA previously granted Fast Track designation and Orphan Drug designation to VGL101 for the treatment of ALSP.

About VGL101

VGL101, Vigil's lead product candidate, is a fully human monoclonal antibody targeting human triggering receptor expressed on myeloid cells 2 (TREM2), which is responsible for maintaining microglial cell function. TREM2 deficiency is believed to be a driver of certain neurodegenerative diseases. VGL101 is in development for rare microgliopathies, such as ALSP, as well as other neurodegenerative diseases for which TREM2 and/or microglia deficiency is believed to be a key driver of disease pathway.

About ALSP

ALSP is a rare, inherited, autosomal dominant neurological disease with high penetrance. It is caused by a mutation to the *CSF1R* gene and affects an estimated 10,000 people in the US, with similar prevalence in Europe and Japan. The disease generally presents itself in adults in their forties, is diagnosed through genetic testing and established clinical/radiologic criteria and is characterized by cognitive dysfunction, neuropsychiatric symptoms, and motor impairment. These symptoms typically exhibit rapid progression with a life expectancy of approximately six to seven years on average after diagnosis, causing significant patient and caregiver burden. There are currently no approved therapies for the treatment of ALSP, underlining the high unmet need in this rare indication.

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 candidate, is a fully human monoclonal antibody agonist targeting human triggering receptor expressed on myeloid 2 (TREM2) and is in a Phase 2 proof-of-concept trial in patients with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP), a rare and fatal neurodegenerative disease. We are also conducting IND-enabling studies with a novel small molecule TREM2 agonist program 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'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 2 proof-of-concept trial and the filing of an IND application for its small molecule TREM2 agonist program; and expectations regarding the development of VGL101 in ALSP and other indications. 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 Annual Report on Form 10-K for the year ended December 31, 2022 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.

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