

**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): December 14, 2022

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.
1 Broadway, 7th Floor, 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 7.01 Regulation FD Disclosure.

On December 14, 2022, the Company issued a press release announcing it had dosed its first patient in the Phase 2, proof-of-concept clinical trial evaluating VGL101. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated December 14, 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: December 14, 2022

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

Vigil Neuroscience Announces First Patient Dosed in the IGNITE Phase 2 Clinical Trial to Evaluate VGL101 in Patients with ALSP

– First-ever interventional trial for patients with ALSP, a rare and rapidly progressing neurological disease with significant unmet medical need –

CAMBRIDGE, Mass., December 14, 2022 (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 the Company dosed its first patient in the Phase 2, proof-of-concept clinical trial evaluating VGL101, a fully human monoclonal antibody TREM2 agonist, in patients with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP).

“Dosing the first ALSP patient in the IGNITE Phase 2 trial represents a significant clinical milestone for Vigil and for people living with this rare, rapidly progressing, fatal disease with a significant unmet need,” said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. “This is also an important first step in reaching our anticipated milestone of establishing proof of concept in ALSP in 2023 and evaluating the therapeutic potential of VGL101 in patients for whom there are currently no approved treatments.”

“Interim topline data from our Phase 1 trial in healthy volunteers demonstrated that VGL101 is safe, well tolerated, brain penetrant, and produced robust and durable reductions in sTREM2, validating its mechanism of action. Now, we look forward to evaluating the safety and tolerability of VGL101 as well as its effects on imaging and biomarkers of disease progression in this first ever interventional trial for people living with ALSP,” said Spyros Papapetropoulos, M.D., Ph.D., Chief Medical Officer of Vigil. “I’d like to thank the Vigil team, study participants, the patient advocacy groups and our clinical collaborators at our trial sites for their tireless efforts in initiating this important trial and their commitment to the ALSP community.”

IGNITE is a global Phase 2, open-label proof-of-concept trial, designed to evaluate the safety and tolerability of VGL101 in up to 15 patients with symptomatic ALSP related to CSF1R gene mutations. Secondary outcome assessments include the effects of VGL101 on magnetic resonance imaging and biomarkers of neurodegeneration and target engagement. Exploratory outcome assessments include the evaluation of clinical efficacy measures using standard cognitive, motor and functional assessments as well as assessment of the pharmacokinetics of VGL101 in patients with ALSP. Patients enrolled in the trial will receive an intravenous (IV) infusion of 20 mg/kg of VGL101 approximately every four weeks, for a treatment duration of one year.

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 maintain 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 cells 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; expectations regarding the development of its small molecule TREM2 agonist program in AD. 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 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 three months ended September 30, 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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