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 18, 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 18, 2024, Vigil Neuroscience, Inc. (the "Company") issued a press release announcing an update on its Phase 2 IGNITE clinical trial. 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 18, 2024, the Company announced that it is updating the clinical development strategy for iluzanebart to preserve the IGNITE Phase 2 clinical trial dataset for a final analysis at 12 months, which the Company believes provides an opportunity to leverage our biomarker strategy and to pursue the potential accelerated approval pathway. As part of this strategy, the Company will not conduct an interim analysis prior to the study completion, and will instead plan to report the final analysis, including all patients at 12 months dosed with either 20 mg/kg or 40 mg/kg of iluzanebart, in the first half 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 timing of the final analysis of the Phase 2 IGNITE clinical trial as well as the success and timing of potential future regulatory interactions regarding the accelerated approval pathway. Factors that could cause actual results to differ include the risks related to delays in the completion of the Company's clinical trials; as well as the risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission (the "SEC"), including the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 and in any subsequent filings it may make with the SEC. 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 18, 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 18, 2024

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

Vigil Neuroscience Provides Update on Clinical Development Strategy to Pursue Potential Accelerated Approval Pathway for Iluzanebart in ALSP

WATERTOWN, Mass., July 18, 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, announced today an update following a Type C Meeting with the U.S. Food and Drug Administration (FDA) to its clinical development strategy for its IGNITE clinical trial evaluating iluzanebart in people with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP).

"We are updating our clinical development strategy to preserve the IGNITE dataset for a final analysis at 12 months, which we believe provides the best opportunity to leverage our biomarker strategy and to pursue the potential accelerated approval pathway. As part of this strategy, we will not conduct an interim analysis prior to the study completion," said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. "This follows a Type C meeting with the FDA where the Agency stated that it was open to considering the accelerated approval pathway and that we should provide additional data to support our proposed development plan. We look forward to continuing to engage with the FDA as we work to bring this potential therapy to patients in need as quickly as possible."

The Company plans to report the final analysis from the IGNITE clinical trial, including all patients at 12 months dosed with either 20 mg/kg or 40 mg/kg of iluzanebart in the first half of 2025.

About IGNITE Clinical Trial

IGNITE is a global Phase 2 clinical trial to evaluate iluzanebart as a treatment for symptomatic ALSP patients who have a confirmed *CSF1R* gene mutation. Patients enrolled in the trial receive an intravenous (IV) infusion of iluzanebart at 20 mg/kg or 40 mg/kg approximately every four weeks for a treatment duration of one year. The trial is evaluating safety, biomarker endpoints, including magnetic resonance imaging (MRI) and neurofilament light chain (NfL), and clinical endpoints using standard cognitive, motor and functional assessments.

About Iluzanebart

Iluzanebart, Vigil's lead clinical 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. Iluzanebart 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 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: the potential therapeutic benefit of iluzanebart, beliefs about observations made analyzing preclinical study and clinical trial data to date; our ability to advance the clinical development of iluzanebart; the progress and timing of the clinical development of Vigil's programs, including the availability of, and expected timing for reporting, final data from the IGNITE Phase 2 clinical trial; and the success and timing of the Company's interactions with regulatory authorities, including with the FDA regarding the accelerated approval pathway. 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 information from the FDA; 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