
**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 25, 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, Suite 07-300
Cambridge, Massachusetts
(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 2.02 Results of Operations and Financial Condition

On March 25, 2022, Vigil Neuroscience, Inc. issued a press release announcing its financial results for the three months and year ended December 31, 2021 (the “Press Release”). A copy of the Press Release is furnished herewith as Exhibit 99.1.

The information set forth under Item 2.02 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 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, 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 March 25, 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: March 25, 2022

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

Vigil Neuroscience Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Highlights

- Completed successful initial public offering, raising \$98 million in gross proceeds -
- Initiated VGL101 Phase 1 trial; Phase 2 trial in ALS patients expected to initiate in 2H 2022 -
- Initiated IND-enabling studies in the small molecule Alzheimer's disease TREM2 agonist program -
- Advanced understanding and awareness of ALS through publication of review article and launch of global patient registry -

CAMBRIDGE, Mass. – March 25, 2022 – 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 financial results for the fourth quarter and full year ended December 31, 2021 and provided an update on recent business highlights.

“This past year and in recent months, we achieved significant milestones. We advanced our lead program, VGL101, an investigational, fully human monoclonal antibody TREM2 agonist, into the clinic and initiated IND-enabling studies in our small molecule TREM2 agonist development program,” said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. “Looking ahead to the second half of 2022, we plan to report topline data from our Phase 1 trial of VGL101 in healthy volunteers, initiate our Phase 2 proof-of-concept trial in ALS patients and begin our Phase 1b biomarker trial in genetically defined populations of Alzheimer's disease patients.”

“We also continued our focus on patient engagement with multiple initiatives including a global patient registry to expand the overall understanding and awareness of ALS, a rare and fatal neurodegenerative disorder that has a significant unmet need. Our goal is to inform our development programs and provide resources and support for patients and caregivers.” continued Dr. Magovčević-Liebisch.

Recent Highlights and Anticipated Milestones

Business Highlights

- **Completed initial public offering in January 2022:** In January 2022, Vigil completed its initial public offering (IPO) of 7,000,000 shares of its common stock at a price to the public of \$14.00 per share. The gross proceeds of the offering were \$98 million, before deducting underwriting discounts and commissions and other offering expenses.
- **Issuance of U.S. patent for VGL101, underpinning anti-TREM2 antibody technology and providing intellectual property protection:** In November 2021, the U.S. Patent and Trademark Office issued U.S. Patent No. 11,186,636, which describes the VGL101 antibody and claims compositions of matter, pharmaceutical compositions and methods of production, each directed to the VGL101 antibody. This underpins the Company's anti-TREM2 antibody technology and provides Vigil with intellectual property protection.

Adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP)

- **Initiated VGL101 Phase 1 trial in healthy volunteers:** Vigil completed dosing of the 20 mg/kg single ascending dose (SAD) cohort without any safety signals and initiated the 20 mg/kg multiple ascending dose (MAD) cohort in its Phase 1 trial, which will inform subsequent clinical trials for VGL101 in ALSP patients as well as patients in other neurodegenerative diseases including genetically defined populations of Alzheimer's disease (AD) patients and cerebral adrenoleukodystrophy.
- **Initiation of the VGL101 ALSP Phase 2 trial remains on track for the second half of 2022:** The Food and Drug Administration (FDA) cleared an Investigational New Drug (IND) for VGL101 in ALSP at doses up to 20 mg/kg, with a partial clinical hold on doses higher than 20 mg/kg. Following Vigil's response to the FDA's initial request for information, as communicated in the agency's partial clinical hold letter, the Company received an updated letter from the FDA requesting additional non-clinical data. Vigil intends to resubmit a response to the FDA in Q2 2022 with new data from a 6-month GLP toxicology study in nonhuman primates as well as Phase 1 clinical data.
- **Natural History Study enrollment is on target:** In September 2021, Vigil initiated a natural history study of ALSP patients to better characterize the patient journey, inform the clinical trial design and facilitate recruitment into its clinical trials.
- **Advanced understanding and awareness of ALSP through publication in *Frontiers in Neurology* and global ALSP patient registry launch:** In February 2022, a review article was published in *Frontiers in Neurology* evaluating the clinical characteristics of ALSP as a foundation for clinical development strategies. The review identifies potential biomarkers for clinical trials for ALSP and highlights key considerations for designing interventional clinical trials to include clinically meaningful efficacy endpoints. In addition, Vigil recently launched the global ALSP patient registry. Data collected from the registry will increase the understanding of patient and caregiver journey, disease burden, health-related quality of life and health economic outcomes, and may be utilized for patient-centric therapeutic development. Further details about the global ALSP patient registry are available at <https://alspregistry.com/>.

Alzheimer's disease (AD)

- **Initiated IND-enabling studies in small molecule TREM2 agonist program:** In the first quarter of 2022, Vigil initiated IND-enabling studies in its novel, small molecule TREM2 agonist program, with an initial focus for the treatment of AD in genetically defined subpopulations. The Company expects to file an IND application in 2023.
- **Initiation of VGL101 Phase 1b trial in genetically defined subpopulations of AD patients remains on track for the second half of 2022:** The Company expects to initiate a Phase 1b biomarker-based clinical trial with VGL101 in genetically defined populations of AD patients with or without the relevant TREM2 variants. This trial will inform the patient segments for subsequent clinical trials with the Company's small molecule candidate.

Fourth Quarter and Full Year 2021 Financial Results

Vigil was incorporated in June 2020. As a result, 2020 financial reporting below represents only partial year results vs 2021 reporting which reflects 12 full months of operations.

- **Cash Position:** Cash and cash equivalents were \$91.4 million as of December 31, 2021, compared to \$24.2 million as of December 31, 2020. Cash and cash equivalents at December 31, 2021 do not include net proceeds of \$88 million from the Company's IPO. Inclusive of the IPO proceeds, the Company expects its cash and cash equivalents to fund its operational plans into 2024.
- **R&D Expenses:** Research and development expenses were \$9.1 million for the quarter and \$32.3 million for the full year ended December 31, 2021, compared to \$3.2 million and \$4.5 million respectively, for the same periods in 2020. The increase for the full year 2021 compared to the prior year was primarily attributable to an increase in internal and external costs related to the continued advancement of the VGL101 and small molecule TREM2 agonist programs.
- **G&A Expenses:** General and administrative expenses were \$3.9 million for the quarter and \$10.1 million for the full year ended December 31, 2021, compared to \$0.9 million and \$1.8 million respectively, for the same periods in 2020. The increase for the full year 2021 compared to the prior year was primarily attributable to increases in headcount-related costs and professional service fees to support the Company's growth as it prepared to operate as a public company.
- **Acquired IPR&D:** In 2020, Vigil in licensed late pre-clinical stage assets from Amgen, which resulted in a one-time expense of \$20.9 million. No such expense was incurred in 2021.
- **Net Loss:** Loss from operations was \$13.0 million for the quarter and \$43.3 million for the full year ended December 31, 2021, compared to \$4.2 million and \$28.5 million respectively, for the same periods in 2020. The increase in net loss for the full year 2021 compared to the prior year was due primarily to higher operating costs in 2021 to support the advancement of the Company's pipeline partially offset by the 2020 IPR&D acquisition.

About ALSP

Adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (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 Asia. The disease generally presents itself in adults in the 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 microglia-focused therapeutics 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.

Forward-Looking Statements

This press release includes certain disclosures that contain “forward-looking statements” that are made pursuant to the safe harbor provisions of the federal securities laws, including, without limitation, statements regarding Vigil Neuroscience’s (“Vigil” or the “Company”) strategy, business plans and focus; the progress and timing of the preclinical and clinical development of Vigil’s programs, including VGL101 and our small molecule TREM2 agonist program; the impact of the ALSP patient registry; expectations regarding the timing and data from the planned clinical update of VGL101 and other pipeline candidates; expectations regarding the intellectual property protection of Vigil’s issued U.S. patent; and expectations regarding the use of capital, expenses and other financial results in 2022 and in the future. 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 from preclinical studies; the timing of the Company’s ability to submit and obtain regulatory clearance for investigational new drug applications and initiate clinical trials; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; 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 and in subsequent filings it may make with the SEC, including its Annual Report on Form 10-K for the year ended December 31, 2021 being filed on or about the date hereof. 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.

Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

| | <u>Three Months Ended</u> | | <u>Year Ended</u> | <u>Period from</u> |
|---|---------------------------|---------------------|---------------------|-----------------------|
| | <u>December 31,</u> | <u>December 31,</u> | <u>December 31,</u> | <u>June 22, 2020</u> |
| | <u>2021</u> | <u>2020</u> | <u>2021</u> | <u>(Inception) to</u> |
| | | | | <u>December 31,</u> |
| | | | | <u>2020</u> |
| Operating expenses: | | | | |
| Related party acquired in-process research and development | \$ — | \$ — | \$ — | \$ 20,923 |
| Research and development | 9,119 | 3,177 | 32,330 | 4,514 |
| General and administrative | 3,858 | 882 | 10,079 | 1,777 |
| Total operating expenses | <u>12,977</u> | <u>4,059</u> | <u>42,409</u> | <u>27,214</u> |
| Loss from operations | <u>(12,977)</u> | <u>(4,059)</u> | <u>(42,409)</u> | <u>(27,214)</u> |
| Other income (expense): | | | | |
| Change in fair value of the related party antidilution obligation | — | (155) | (836) | (1,307) |
| Change in fair value of Series A preferred stock tranche obligation | — | (21) | (28) | (24) |
| Interest income, net | — | — | 3 | — |
| Other expense, net | (8) | (1) | (13) | (1) |
| Total other expense, net | <u>(8)</u> | <u>(177)</u> | <u>(874)</u> | <u>(1,332)</u> |
| Net loss and comprehensive loss | <u>\$ (12,985)</u> | <u>\$ (4,236)</u> | <u>\$ (43,283)</u> | <u>\$ (28,546)</u> |
| Net loss per share attributable to common stockholders, basic and diluted | <u>\$ (8.28)</u> | <u>\$ (2.86)</u> | <u>\$ (28.26)</u> | <u>\$ (21.15)</u> |
| Weighted—average common shares outstanding, basic and diluted | <u>1,567,303</u> | <u>1,480,687</u> | <u>1,531,686</u> | <u>1,349,702</u> |

VIGIL NEUROSCIENCE, INC.
Selected Balance Sheet Data
(in thousands)
(unaudited)

| | <u>December 31, 2021</u> | <u>December 31, 2020</u> |
|-----------------------------|--------------------------|--------------------------|
| Cash and cash equivalents | \$ 91,420 | \$ 24,151 |
| Total assets | 102,441 | 25,296 |
| Total liabilities | 9,945 | 6,545 |
| Total stockholders' deficit | (69,443) | (28,283) |

Investor Contact:

Sarah Carmody
scarmody@vigilneuro.com

Media Contact:

Megan McGrath
MacDougall Advisors
mmcgrath@macdougall.bio

###