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 1, 2020

OVID THERAPEUTICS INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38085**	**46-5270895**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
1460 Broadway, Suite 15044 New York, New York		**10036**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 646-661-7661

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 (see General Instructions A.2. below):

☐ 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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock par value $0.001 per share	OVID	The Nasdaq Stock Market LLC

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 8.01. Other Events.

NEPTUNE Phase 3 Clinical Trial

On December 1, 2020, Ovid Therapeutics Inc. (the "***Company***") issued a press release announcing that its Phase 3 Neptune clinical trial of OV101 for the treatment of Angelman syndrome did not meet its primary endpoint. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Angelini Collaboration

On November 25, 2020, the Company received a $5 million milestone payment from Angelini Pharma Rare Diseases AG ("***Angelini***") for the completion of the technology transfer and compound delivery in accordance with its License and Collaboration Agreement with Angelini.

Item 9.01. Financial Statements and Exhibits

(d) Exhibit

Exhibit No.	Description
99.1	Press Release, dated December 1, 2020

SIGNATURES

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.

OVID THERAPEUTICS INC.

By: /s/ Thomas M. Perone
Thomas M. Perone
General Counsel & Corporate Secretary

Dated: December 1, 2020

Ovid Therapeutics Announces Phase 3 NEPTUNE Clinical Trial of OV101 for the Treatment of Angelman Syndrome Did Not Meet Primary Endpoint

- OV101 program in Angelman syndrome to pause pending full analysis of NEPTUNE trial and discussions with FDA
- Pivotal studies of OV935 (soticlestat) in Dravet syndrome and Lennox-Gastaut syndrome expected to begin in the First Half of 2021

NEW YORK, December 1, 2020 -- Ovid Therapeutics Inc. (NASDAQ: OVID), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological diseases, today announced topline results from the Company's Phase 3 NEPTUNE clinical trial of OV101 (gaboxadol) for the treatment of Angelman syndrome.

NEPTUNE is a randomized, double-blind, placebo-controlled, Phase 3 study that enrolled and treated 97 patients diagnosed with Angelman syndrome, 4-12 years of age, and 7 patients diagnosed with Angelman syndrome ages 2-3 years for safety and pharmacokinetic evaluation only. The study was designed to assess the effects of treatment with OV101 (oral, once-daily dosing) versus placebo over 12 weeks. The sole primary endpoint was change in overall score on the Clinical Global Impression-Improvement-Angelman syndrome (CGI-I-AS) scale. Secondary endpoints included sleep, communication, motor function, socialization, daily living skills and behavior domains.

The primary endpoint of the NEPTUNE study was not achieved. Patients given OV101 showed a 0.7 point improvement in CGI-I-AS over baseline while placebo also showed a 0.8 point improvement in CGI-I-AS (p=NS). Secondary endpoints continue to be evaluated, although initial results show no difference between OV101 and placebo.

OV101 was well-tolerated, with no significant safety issues observed. Ovid plans to complete a full analysis of the results of the NEPTUNE study and discuss these results with the U.S. Food and Drug Administration (FDA) to determine next steps, if any, for the program. The Company will continue to offer study drug to patients enrolled in the open-label exention trial (ELARA) pending further analysis of the NEPTUNE study. The Company expects to report data from the ELARA study in the first quarter of 2021.

"We are deeply disappointed with the outcome of the NEPTUNE trial which did not achieve its primary endpoint," said Jeremy Levin, DPhil, MB, BChir, Chairman and Chief Executive Officer of Ovid Therapeutics. "Other than the ongoing ELARA study, we plan to pause our OV101 program in Angelman syndrome pending a full understanding of this outcome and discussions with regulators and investigators."

Dr. Levin added: “For now, the focus of our future development efforts will concentrate on the development of our other late-stage asset, OV935, in two rare epilepsies: Dravet and Lennox-Gastaut syndromes. With our partner Takeda, we plan to intiate pivotal trials in these conditions in the first half of 2021.”

“NEPTUNE is our first study focused on the pediatric and adolescent population in Angelman syndrome, and we will fully assess all the data from this trial to understand this outcome and determine next steps, if any, for OV101 in this and other conditions, including Fragile X syndrome,” said Amit Rakhit M.D., President and Chief Medical Officer. “We are sincerely grateful for the commitment and dedication of patients, families, investigators and employees to this program, and in particular, to those who participated in the NEPTUNE trial.”

About OV101 (gaboxadol)
OV101 (gaboxadol) is a delta (δ)-selective GABAA receptor agonist. These receptors are thought to have a central role in tonic inhibition, a key physiological process of the brain believed to be a core pathophysiology underlying certain neurodevelopmental disorders.

About Angelman Syndrome
Angelman syndrome is a rare genetic condition that is characterized by a variety of signs and symptoms. Characteristic features of this condition include delayed development, intellectual disability, severe speech impairment, problems with movement and balance, seizures, sleep disorders and anxiety.

About Ovid Therapeutics
Ovid Therapeutics Inc. is a New York-based biopharmaceutical company using its BoldMedicine® approach to develop medicines that transform the lives of patients with rare neurological disorders. Ovid has a broad pipeline of potential first-in-class medicines in development. The Company is developing OV935 (soticlestat) in collaboration with Takeda Pharmaceutical Company Limited for the potential treatment of rare developmental and epileptic encephalopathies (DEEs). OVID is evaluating OV101 (gaboxadol) for the treatment of Angelman syndrome and Fragile X syndrome. For more information on Ovid, please visit www.ovidrx.com.

Forward-Looking Statements
This press release includes certain disclosures that contain “forward-looking statements,” including, among other things, statements regarding uncertainties regarding the impact of the NEPTUNE trial results on the clinical development of OV101 in Angelman syndrome, likelihood that data will support future development, the association of data with treatment outcomes, the design, progress, timing, scope and results of the Company’s clinical trials, the anticipated timing of disclosure of results of clinical trials and the likelihood of obtaining regulatory approval of Ovid’s product candidates. You can identify forward-looking statements because they contain words such as “will,” “appears,” “believes” and “expects.” Forward-looking statements are based on Ovid’s current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements include uncertainties in the development and regulatory approval processes, and the fact that initial data from clinical trials may not be indicative, and are not guarantees, of the final results of the clinical trials and are subject to the risk that one or more of the clinical

outcomes may materially change as patient enrollment continues and/or more patient data become available. Additional risks that could cause actual results to differ materially from those in the forward-looking statements are set forth in Ovid's filings with the Securities and Exchange Commission under the caption "Risk Factors." Such risks may be amplified by the COVID-19 pandemic and its potential impact on Ovid's business and the global economy. Ovid assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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