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 6, 2018

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)**	**(I.R.S. Employer Identification No.)**

1460 Broadway, Suite 15044 **New York, New York** **(Address of principal executive offices)**	**10036** **(Zip Code)**

Registrant's telephone number, including area code: (646) 661-7661

(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 Instruction 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))

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.

On December 6, 2018, Ovid Therapeutics Inc. (the "Company") issues a Press Release announcing plans to move into a Phase 3 Trial in Pediatric Patients Based on End-of-Phase 2 Meeting for OV101 in Angelman Syndrome.

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.

Item 9.01. Financial Statements and Exhibits

(d) Exhibit

Exhibit No.	**Description**
99.1	Press Release, dated December 6, 2018

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/ Ana C. Ward
Ana C. Ward
Senior Vice President, General Counsel

Dated: December 6, 2018

Exhibit 99.1

Ovid Therapeutics Announces Plans to Move into a Phase 3 Trial in Pediatric Patients Based on End-of-Phase 2 Meeting for OV101 in Angelman Syndrome

-- Single pivotal Phase 3 trial design, using once-daily dosing, may be sufficient for approval of OV101 in Angelman syndrome--

-- Trial initiation activities have begun for ELARA, an open-label extension study for patients with Angelman syndrome who completed any prior OV101 clinical trial --

NEW YORK, Dec. 6, 2018 – Ovid Therapeutics Inc. (NASDAQ:OVID), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological diseases, today announced plans to move ahead with a single pivotal Phase 3 trial of OV101 in pediatric patients with Angelman syndrome based on its End-of-Phase 2 Meeting with the U.S. Food and Drug Administration (FDA). If successful, the Phase 3 efficacy and safety trial called NEPTUNE is intended to support a New Drug Application (NDA) for OV101 in Angelman syndrome. OV101 is a novel delta (δ)-selective GABAA receptor agonist.

Angelman syndrome is a rare genetic disorder that is characterized by a heterogeneous constellation of symptoms, including disturbances in communication, sleep, motor function, and behavior, and for which there are no approved medicines or established treatment paradigms.

Based upon review and discussion of the Phase 2 STARS trial results, the clinical trial design, and the applicability of Clinical Global Impressions of Improvement (CGI-I) as a primary endpoint, the FDA and Ovid are in general agreement that the pivotal Phase 3 NEPTUNE clinical trial to be completed prior to an NDA submission, will include the following elements:

- Single 12-week, two-arm, randomized, double-blind, placebo-controlled trial
- Once-daily dose
- Approximately 50-60 pediatric patients aged 4 to 12 years, diagnosed with Angelman syndrome randomized to either placebo or OV101
- Primary endpoint of change in overall CGI-I score

CGI-I will be used as a single primary endpoint, mainly due to the rare nature of Angelman syndrome, the lack of treatment options, the nonexistence of assessment instruments specific to Angelman syndrome, the heterogeneity of the disorder, and the lack of sensitivity or appropriateness of other validated measures. Based on feedback from the FDA, Ovid will develop a framework for study investigators to ensure uniform use of the validated CGI-I scale by focusing on specific symptoms that are relevant and important to patients with Angelman syndrome and their caregivers.

Ovid expects to begin enrollment of the NEPTUNE trial in the second half of 2019, pending FDA concurrence on the study protocol and supporting framework and materials. Updates and further details of this trial, including secondary endpoints, will be provided upon trial initiation.

“It is important to acknowledge that while this meeting was a milestone for Ovid, and provides a clear path forward, it is an even more momentous one for the Angelman syndrome community,” said Jeremy Levin, DPhil, MB, BChir, chairman and chief executive officer of Ovid Therapeutics. “From the relationships we have formed within the community, to the completion of the first industry-sponsored trial in Angelman syndrome, we are very encouraged by the clinical progress we’ve made. With the thoughtful assistance and clear direction from the FDA, we now move forward to a pivotal trial that we hope will result in the first approved medicine for individuals living with this disorder.”

“The End-of-Phase 2 Meeting was productive and helped us understand the FDA’s expectations for a pivotal trial of OV101 in Angelman syndrome,” said Amit Rakhit, M.D., MBA, chief medical and portfolio management officer of Ovid Therapeutics. “As with many rare genetic disorders, symptoms of Angelman syndrome usually appear early in childhood, and persist and evolve into adulthood. We have completed juvenile toxicology studies which, in addition to our pharmacokinetic/pharmacodynamic (PK/PD) data, provide the basis for initiating a pivotal trial in younger patients. This trial is not only an important next step of our OV101 strategy, but also part of our overall mission to bring medicines to people who have no or limited treatment options.”

In addition to the planned Phase 3 NEPTUNE trial, Ovid is initiating the ELARA clinical trial, an open-label extension study for individuals with Angelman syndrome who have completed any prior OV101 study. ELARA will use once-daily dosing and will assess long term safety and tolerability in addition to efficacy measures. Trial initiation activities are underway. The Company is also exploring options for patients under four years of age.

Phase 2 STARS Trial Design and Results
STARS was a 12-week, double-blind, placebo-controlled Phase 2 trial which enrolled eighty-eight patients (adults, n=66; adolescents, n=22) 13 to 49 years of age diagnosed with Angelman syndrome. The study randomized patients to one of three arms: once-daily (QD) dose of OV101 at night (15 mg), twice-daily (BID) dose of OV101 (10 mg in the morning and 15 mg at night), and placebo.

The primary endpoint of the STARS trial was to assess the safety and tolerability of OV101 compared to placebo. The STARS trial also explored the clinical utility of OV101 on improvements in clinical global impressions, behavior, sleep, and gross and fine motor skills.

Comprehensive data from STARS were provided in a press release issued October 25, 2018.

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

disorders and anxiety. The most common cause of Angelman syndrome is the loss of function of the gene that codes for ubiquitin protein ligase E3A (UBE3A), which plays a critical role in nerve cell communication, resulting in impaired tonic inhibition. Individuals with Angelman syndrome are highly social with a typical lifespan; but are unable to live independently, therefore, they require constant support from a network of specialists and caregivers. Angelman syndrome affects approximately 1 in 12,000 to 1 in 20,000 people in the U.S. There are currently no approved therapies for the treatment of Angelman syndrome.

Angelman syndrome is associated with a reduction in tonic inhibition, a function of the delta (δ)-selective GABAA receptor that allows a human brain to decipher excitatory and inhibitory neurological signals correctly without being overloaded. If tonic inhibition is reduced, the brain becomes inundated with signals and loses the ability to separate background noise from critical information.

About OV101
OV101 (gaboxadol) is believed to be the only delta (δ)-selective GABAA receptor agonist in development and the first investigational drug to specifically target the disruption of tonic inhibition, a central physiological process of the brain that is thought to be the underlying cause of certain neurodevelopmental disorders. OV101 has been demonstrated in laboratory studies and animal models to selectively activate the δ-subunit of GABAA receptors, which are found in the extrasynaptic space (outside of the synapse), and thereby impact neuronal activity through tonic inhibition.

Ovid is developing OV101 for the treatment of Angelman syndrome and Fragile X syndrome to potentially restore tonic inhibition and relieve several of the symptoms of these disorders. In preclinical studies, it was observed that OV101 improved symptoms of Angelman syndrome and Fragile X syndrome. This compound has also previously been tested in over 4,000 patients (over 1,000 patient-years of exposure) and was observed to have favorable safety and bioavailability profiles.

The FDA has granted Orphan Drug and Fast Track designations for OV101 for both the treatment of Angelman syndrome and Fragile X syndrome. The U.S. Patent and Trademark Office has granted Ovid patents directed to methods of treating Angelman syndrome and Fragile X syndrome using OV101. The issued patents expire in 2035 without regulatory extensions.

About Ovid Therapeutics
Ovid Therapeutics (NASDAQ: OVID) 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. The company's lead investigational medicine, OV101, is currently in development for the treatment of Angelman syndrome and Fragile X syndrome. Ovid is also developing OV935/TAK-935 in collaboration with Takeda Pharmaceutical Company Limited for the treatment of rare developmental and epileptic encephalopathies (DEE).

For more information on Ovid, please visit http://www.ovidrx.com/.

Forward-Looking Statements
This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding the potential clinical benefit of OV101 to treat patients with Angelman syndrome; the timing and results of future clinical milestones with OV101; the timing and scope of any future clinical trials and results of any such clinical trials with OV101; the potential for a single Phase 3 pivotal trial to support the basis for an NDA submission or approval of OV101 in Angelman syndrome by any regulatory authority; the timing and results of any discussions with regulatory agencies on the Phase 3 trial design including, but not limited to, the study protocol and the framework for the use of CGI-I in the Angelman syndrome population; and the timing and outcomes of future interactions with regulatory bodies. You can identify forward-looking statements because they contain words such as "will," "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 are set forth in Ovid's filings with the Securities and Exchange Commission under the caption "Risk Factors." 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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