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): January 4, 2019

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 January 4, 2019, Ovid Therapeutics Inc. (the "Company") issues a Press Release outlining 2019 Clinical and Business Priorities.

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 January 4, 2019

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: January 4, 2019

Exhibit 99.1

Ovid Therapeutics Outlines 2019 Clinical and Business Priorities

*-- **OV101 in Angelman syndrome**: Pivotal Phase 3 NEPTUNE trial expected to begin in second half 2019 --*

*-- **OV101 in Fragile X syndrome**: Phase 2 ROCKET clinical trial results in adolescents and young adults expected in second half 2019 --*

*-- **OV935/TAK-935 in rare developmental and epileptic encephalopathies**: Recent results from Phase 1b/2a trial in adults expected to bolster current clinical development program in children; enrollment in ARCADE trial in CDKL5 deficiency disorder and Duplication 15 syndrome expected to complete in second half 2019 --*

NEW YORK, January 4, 2019 – Ovid Therapeutics Inc. (NASDAQ:OVID), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological diseases, today outlined key clinical and business priorities for 2019.

"2018 was a year of exciting clinical achievement and disciplined corporate execution, as we made important steps forward in two rare disorders with significant unmet medical needs: Angelman syndrome and rare developmental epilepsies," said Jeremy Levin, DPhil, MB, BChir, chairman and chief executive officer of Ovid Therapeutics. "Two events announced in December 2018 created a very solid foundation for progress in 2019 and beyond. Specifically, following our End-of-Phase 2 meeting with the FDA, we have a clear and realistic development path for our Angelman syndrome program, paving the way for the first potential treatment for a disorder with no approved medicines anywhere in the world. Similarly, we are very encouraged about the potential of OV935 to treat rare developmental and epileptic encephalopathies (DEE). Our pre-clinical research and Phase 1b/2a results suggest OV935 may have anti-ictal as well as anti-epileptogenic properties, which could represent a new medical option to treat these devastating epilepsies.

"In 2019, the anticipated start of our pivotal Phase 3 trial in Angelman syndrome, results from our Phase 2 ROCKET trial for OV101 in Fragile X syndrome, and the continued progress of our Phase 2 trials from our broad development program in DEE for OV935 each has the potential to redefine the way patients and families are living with these rare disorders."

2018 Highlights and Anticipated 2019 Clinical and Regulatory Milestones

OV101 for Angelman Syndrome
A novel delta (δ)-selective GABAA receptor agonist entering Phase 3 clinical development.

Based on results announced in 2018 for the Phase 2 STARS clinical trial and discussion with the U.S. Food and Drug Administration (FDA) during an End-of-Phase 2 meeting, Ovid announced plans on December 6, 2018 to move ahead with a single pivotal Phase 3 trial of OV101 in pediatric patients with Angelman syndrome, called NEPTUNE, pending FDA concurrence on the study protocol and supporting framework and materials. If positive, NEPTUNE is intended to support a New Drug Application for OV101.

In 2019, Ovid expects to achieve the following key milestones for its Angelman syndrome program:

- Enroll first patient in the ELARA trial, an open-label extension study, in the first quarter of 2019.
- Submit Phase 2 STARS clinical results for publication in a peer-reviewed medical journal.
- Finalize protocol and operational plans for Phase 3 NEPTUNE trial and submit to FDA in the first half of 2019.
- Initiate enrollment for Phase 3 NEPTUNE trial in the second half of 2019.
- Engage with European Medicines Agency (EMA) on OV101 clinical development plans.

OV101 for Fragile X Syndrome

In July 2018, Ovid initiated the Phase 2 ROCKET clinical trial, a randomized, double-blind, parallel-group trial to evaluate the safety, tolerability and efficacy of OV101 over 12 weeks in approximately 30 males with Fragile X syndrome aged 13 to 22 years. The SKY ROCKET trial was initiated in the third quarter of 2018 and is an observational study designed to provide additional data on the key endpoints being explored in the ROCKET trial. It is also designed to provide comparative data with the current standard of care. SKY ROCKET will enroll up to 30 males with Fragile X syndrome ages 5 to 30 years.

In 2019, Ovid expects to achieve the following key milestones for OV101's Fragile X syndrome program:

- Complete enrollment in Phase 2 ROCKET trial; announce data in second half 2019.
- Complete enrollment in Phase 2 SKY ROCKET; announce data in second half 2019.

OV935 for Rare Developmental and Epileptic Encephalopathies (DEE)

A potent, highly-selective, first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H) being investigated as a novel approach to treating epilepsy. OV935 is being developed in the context of a unique collaboration with Takeda Pharmaceutical Company Limited. The companies share 50 percent of all development expenses and potential future revenues.

In a press release issued December 17, 2018, Ovid announced results from the Phase 1b/2a clinical trial of OV935 in 18 adults with rare DEE who had not been successfully treated with currently available treatment regimens. The trial achieved its primary endpoint of safety and tolerability, showing OV935 to be generally well tolerated. Exploratory efficacy analysis of OV935 showed progressive reduction over time in seizure frequency that was correlated with decreases in plasma 24-hydroxycholesterol (24HC) levels in adults across multiple DEE.

Ovid expects to achieve the following key milestones in 2019 for the OV935 development program:

- Submit Phase 1b/2a clinical trial results for peer-review presentation at a scientific medical meeting in first half 2019.
- Engage with EMA on OV935 clinical development plans.
- Continue enrollment in ENDYMION open-label extension trial.
- Complete enrollment in the second half of 2019 in the Phase 2 ARCADE trial, an open-label trial evaluating patients 2 to 17 years of age diagnosed with CDKL5 deficiency disorder and Duplication 15q syndrome.
- Continue enrollment in Phase 2 ELEKTRA trial, a randomized, double-blind, placebo-controlled trial evaluating patients 2 to 17 years of age diagnosed with Dravet syndrome and Lennox-Gastaut syndrome.
- Continue to evaluate the potential for plasma 24HC to be a biomarker.

Corporate

- Continue to evaluate ex-U.S. licensing opportunities and potential partnerships that could accelerate the development of OV101 in Angelman and Fragile X syndromes and other potentially broader areas and could also provide potential non-dilutive forms of capital.

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 progress, timing, scope and results of clinical trials for Ovid's product candidates, the reporting of clinical data regarding Ovid's product candidates, the study of the role of 24-S-hydroxycholesterol (24HC) as a plasma-based biomarker, the publication of data in medical journals, the timing and outcome of future interactions with regulatory authorities, the approval or registration of Ovid's product candidates by regulatory authorities, and the completion of any licensing or partnership agreements. 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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