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 7, 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.

On January 7, 2020, Ovid Therapeutics Inc. (the "Company") issued a Press Release announcing their 2020 Update in Preparation for Multiple Clinical Data Readouts Across Rare Neurological Disease Platform.

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 7, 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: January 07, 2020

Exhibit 99.1

Ovid Therapeutics Provides 2020 Update in Preparation for Multiple Clinical Data Readouts Across Rare Neurological Disease Platform

OV101 (gaboxadol) in Neurodevelopmental Disorders:

- *Topline Results From Pivotal Phase 3 NEPTUNE Trial in Angelman Syndrome Expected in Mid-2020*
- *Results From Phase 2 Signal-Finding ROCKET Trial and SKY ROCKET Non-Interventional Data in Fragile X Expected by Early Q2 2020*

OV935/TAK935 (soticlestat) in Rare Developmental and Epileptic Encephalopathies (DEE):

- *Data from Randomized Phase 2 ELEKTRA Trial in Children with Dravet Syndrome or Lennox-Gastaut Syndrome Expected in 2H 2020*
- *Initial Data from Phase 2 ARCADE Trial in Dup15q Syndrome or CDKL5 Deficiency Disorder Expected in Q1 2020*
- *Additional Clinical Data From ENDYMION Open Label Extension Study Expected in Q1 2020*

NEW YORK, January 7, 2020 – 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 2020.

“Our focus in 2019 was on execution, building our senior leadership team and strengthening our balance sheet. As we look ahead to 2020, we enter the year in a strong financial position and will start to realize the potential impact that our hard work can deliver with multiple important clinical data readouts anticipated throughout the year,” said Jeremy Levin, DPhil, MB, BChir, chairman and chief executive officer of Ovid Therapeutics. “We expect new late-stage data from our two lead programs and across multiple indications in 2020. We will report the results of our pivotal Phase 3 NEPTUNE trial which, if successful, would make gaboxadol the first-ever treatment for Angelman syndrome. In addition, we will report data from the Phase 2 ROCKET signal-finding trial in Fragile X syndrome, a program that has the potential to provide a clinical path forward in this poorly served area. Finally, we are very excited to report updated data from soticlestat in rare epilepsies, which we believe could provide a clinically meaningful benefit to these patients who have limited options. 2020 is poised to be a pivotal year for our company and importantly, for the patients and families for which we strive every day to help.”

For a full summary of 2020 clinical data milestones, please visit the Investors section of the Ovid Therapeutics website.

Clinical Data Readouts Expected in 2020

Gaboxadol for Angelman Syndrome
Ovid continues to enroll patients in the pivotal Phase 3 NEPTUNE trial in Angelman syndrome, with topline results expected in mid-2020. The randomized, double-blind, placebo-controlled trial is designed to assess the effects of treatment with gaboxadol (oral, once-daily dosing) versus placebo over 12 weeks. The sole primary endpoint is change in overall score on the Clinical Global Impression-Improvement-Angelman syndrome (CGI-I-AS) scale.

NEPTUNE, if positive, will be part of a broad data set intended to support registrational filings for gaboxadol in the U.S. and rest of world. There are currently no other therapies in clinical development for Angelman syndrome, and if approved, gaboxadol would be the first medicine available for individuals with Angelman syndrome.

Soticlestat for Rare Developmental and Epileptic Encephalopathies (DEE)
Soticlestat is being evaluated in a comprehensive Phase 2 development program in DEE in collaboration with Takeda Pharmaceutical Company Limited.

In September 2019, Ovid announced initial data from the ongoing Phase 2 open-label extension ENDYMION trial, demonstrating sustained and progressively-improving median seizure frequency reduction. Ovid plans to announce longer-term data from the ENDYMION open-label extension study in Q1 2020.

Beyond the ENDYMION open-label extension study, Ovid and Takeda are also conducting the Phase 2 ARCADE and ELEKTRA trials in pediatric DEE patient populations.

Initial data from the Phase 2 ARCADE study are expected in Q1 2020. ARCADE is a multicenter, open-label, pilot study that will evaluate the treatment of soticlestat in patients ages 2 to 35 years old with refractory epileptic seizures associated with CDKL5 Deficiency Disorder (CDD) or Dup15q syndrome. The primary endpoint is the percent change in motor seizure frequency in patients treated with soticlestat by disorder.

Topline results from the Phase 2 ELEKTRA study are expected in 2H 2020. ELEKTRA is an international, multicenter, randomized, double-blind, placebo-controlled study that will evaluate the treatment of soticlestat in approximately 126 pediatric patients ages 2 to 17 years old with seizures associated with Dravet syndrome or Lennox-Gastaut syndrome (LGS). The primary endpoint is the percent change from baseline in seizure frequency in patients treated with soticlestat compared to placebo.

Despite the availability of medicines for epilepsy generally, there are few or no approved therapies for specific DEEs. Novel therapies are needed as current therapies fail to alter the course of the disease or address co-morbidities, and many patients suffer from resistant seizures despite treatment with multiple anti-epileptic drugs.

Gaboxadol for Fragile X Syndrome

Ovid expects results from the Phase 2 ROCKET trial and the SKY ROCKET non-interventional trial, in Fragile X syndrome by early Q2 2020.

The ROCKET trial is a signal-finding, randomized, double-blind, parallel-group trial to evaluate the safety, tolerability and efficacy of gaboxadol in males ages 13 to 22 with a confirmed diagnosis of Fragile X syndrome. The primary objective of the study is safety and tolerability of gaboxadol over 12 weeks of treatment in three different active-arm cohorts. The secondary objective is to evaluate changes in behavior after 12 weeks of treatment using the ABC-C scale adapted for Fragile X syndrome (ABC-FXS).

SKY ROCKET is a non-drug study of males ages 5 to 30 with a confirmed diagnosis of Fragile X to assess the suitability of scales for the measurement of behavior, sleep and functioning. This trial is designed to provide additional data on the key endpoints that are being explored in ROCKET and provide comparative data on the benefit offered by the standard-of-care.

There are no approved treatments for Fragile X syndrome.

2020 Educational Program

Ovid will continue to undertake a broad educational program to further review its pipeline and clinical endpoints relevant to neurodevelopmental disorders with key constituencies, including scientists, external clinician experts and patient advocacy groups.

About OV101 (gaboxadol)

Gaboxadol is believed to be the only delta (δ)-selective GABA $_A$ 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. Gaboxadol has been demonstrated in laboratory studies and animal models to selectively activate the δ-subunit of $GABA_A$ receptors, which are found in the extrasynaptic space (outside of the synapse), and thereby impact neuronal activity through modulation of tonic inhibition.

Ovid is developing gaboxadol for the treatment of Angelman syndrome and Fragile X syndrome to potentially restore tonic inhibition and thereby address several core symptoms of these disorders. In both these syndromes, the underlying pathophysiology includes disruption of tonic

inhibition modulated through the δ-subunit of $GABA_A$ receptors. In preclinical studies, it was observed that gaboxadol improved symptoms of Angelman syndrome and Fragile X syndrome. This compound has also previously been tested in more than 4,000 patients (more than 1,000 patient-years of exposure) and was observed to have favorable safety and bioavailability profiles. In 2018, Ovid announced the successful completion of its Phase 2 (STARS) trial of gaboxadol in adults and adolescents with Angelman syndrome. Ovid is conducting a pivotal Phase 3 clinical trial in Angelman syndrome (NEPTUNE) as well as a Phase 2 signal-finding clinical trial in Fragile X syndrome (ROCKET).

The FDA has granted Orphan Drug and Fast Track designations for gaboxadol for both the treatment of Angelman syndrome and Fragile X syndrome. The European Commission (EC) has granted orphan drug designation to gaboxadol for the treatment of Angelman syndrome. The U.S. Patent and Trademark Office has granted Ovid patents directed to methods of treating Angelman syndrome and Fragile X syndrome using gaboxadol. The issued patents expire in 2035 without regulatory extensions.

About OV935/TAK935 (soticlestat)
Soticlestat is a potent, highly-selective, first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H), with the potential to reduce seizure susceptibility and improve seizure control. CH24H is predominantly expressed in the brain, where it converts cholesterol into 24S-hydroxycholesterol (24HC) to adjust the homeostatic balance of brain cholesterol. 24HC is a positive allosteric modulator of the NMDA receptor and modulates glutamatergic signaling associated with epilepsy. Glutamate is one of the main neurotransmitters in the brain and has been shown to play a role in the initiation and spread of seizure activity. Recent literature indicates that CH24H is involved in over-activation of the glutamatergic pathway through modulation of the NMDA channel and that increased expression of CH24H can disrupt the reuptake of glutamate by astrocytes, resulting in epileptogenesis and neurotoxicity. Inhibition of CH24H by soticlestat reduces the neuronal levels of 24HC and may improve excitatory/inhibitory balance of NMDA channel activity. To Ovid's knowledge, soticlestat is the only molecule with this mechanism of action in clinical development as an anti-epileptic drug (AED).

Ovid and Takeda are conducting a comprehensive Phase 2 clinical development program with soticlestat in people with Developmental and Epileptic Encephalopathies (DEE), a heterogeneous group of rare highly-refractory epilepsy syndromes that encompasses Dravet syndrome, Lennox-Gastaut syndrome (LGS), and others.

The United States Food and Drug Administration (FDA) has granted orphan drug designation to soticlestat for the treatment of both Dravet syndrome and Lennox-Gastaut syndrome (LGS).

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. The company's most advanced investigational medicine, OV101 (gaboxadol), is currently in clinical development for the treatment of Angelman syndrome and Fragile X syndrome. Ovid is also developing OV935/TAK935 (soticlestat) in collaboration with Takeda Pharmaceutical Company Limited for the potential 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: advancing and commercializing Ovid's product candidates, progress, timing, scope and the potential therapeutic benefits based on results of clinical trials for Ovid's product candidates; and the anticipated reporting schedule of clinical data regarding Ovid's product candidates. You can identify forward-looking statements because they contain words such as "will," "believes" and "expects" and similar expressions intended to identify statements about the future. 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 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". 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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