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): July 2, 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)**	**(IRS 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

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))

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. ☒

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

Item 8.01. Other Events.

On July 2, 2019, Ovid Therapeutics Inc. issued a Press Release announcing that the European Commission has granted orphan drug designation to OV101 (gaboxadol) for the treatment of 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 July 2, 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/ Thomas M. Perone
Thomas M. Perone
General Counsel & Corporate Secretary

Dated: July 2, 2019

Exhibit 99.1

Ovid Therapeutics Receives Orphan Drug Designation from the European Commission for OV101 for the Treatment of Angelman Syndrome

NEW YORK – July 2, 2019 – Ovid Therapeutics Inc. (NASDAQ: OVID), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological diseases, today announced that the European Commission (EC) has granted orphan drug designation (ODD) to OV101 (gaboxadol) for the treatment of Angelman syndrome based on the results of the Phase 2 STARS trial. OV101 is believed to be the only delta (δ)-selective $GABA_A$ receptor agonist in clinical development for the treatment of certain neurodevelopmental disorders, including Angelman syndrome.

"We are proud to be granted Orphan Drug Designation by the European Commission. This is another important step and further validates the potential of OV101 to be a meaningful treatment option for those living with Angelman syndrome around the world," said Amit Rakhit, MD, MBA, Chief Medical Officer and Head of Research & Development at Ovid. "Today, there are no approved medicines specifically for Angelman syndrome. Ovid previously received Orphan Drug and Fast Track designation for OV101 from the U.S. Food and Drug Administration (FDA). We recently announced we have initiated the pivotal Phase 3 NEPTUNE trial in Angelman syndrome and have a clear route to registration, if positive."

Dr. Rakhit continued, "It is believed that in the U.S. there are approximately 24,000 individuals with Angelman syndrome and a similar number in the European Union. OV101 is the only medicine currently in clinical development for Angelman syndrome. It's our intent for OV101 to be the first medicine to be approved for this important and underserved community."

About Orphan Drug Designation by the European Medicines Agency
About 30 million people in the European Union (EU) live with a rare disease. ODD in the EU is granted by the EC based on a positive opinion by the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) to companies developing therapies to diagnose, prevent or treat a rare disease. To qualify for ODD, a potential medicine must target a life-threatening or chronically debilitating disease that affects no more than 5 in 10,000 persons in the EU. Additionally, the investigational medicinal product must either provide a significant benefit over existing therapies or provide a treatment for patients for whom existing therapies do not work or exist. The designation enables a company to benefit from incentives in the EU, such as reduced fees, centralized authorization and protection from competition for ten years once the medicine is approved for marketing.

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 typically have normal lifespans 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 globally.

There are no approved therapies for Angelman syndrome, and treatment primarily consists of behavioral interventions and pharmacologic management of symptoms.

Angelman syndrome is associated with a reduction in tonic inhibition, a function of the delta (δ)-selective $GABA_A$ 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 $GABA_A$ 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. OV101 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 tonic inhibition.

Ovid is developing OV101 for the treatment of Angelman syndrome and Fragile X syndrome to potentially restore tonic inhibition and thereby address the core symptoms of these disorders. In both of these syndromes, the underlying pathophysiology includes disruption of the tonic inhibition modulated through the δ-subunit of $GABA_A$ receptors. 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. In 2018, Ovid announced the successful completion of its Phase 2 STARS trial of OV101 in adults and adolescents with Angelman syndrome. Ovid expects to enroll the first patients in the pivotal Phase 3 (NEPTUNE) clinical trial in children aged 4-12 years old with Angelman syndrome during the third quarter of 2019. In addition, Ovid is conducting a Phase 2 clinical trial (ROCKET) in Fragile X syndrome, with results expected around year-end 2019 or early 2020.

The FDA has granted Orphan Drug and Fast Track designations for OV101 for both the treatment of Angelman syndrome and Fragile X syndrome.

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 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 (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 Ovid's product candidates, progress, timing, scope and results of clinical trials for Ovid's product candidates, and the reporting of clinical data regarding Ovid's product candidates. 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.

Contacts

Investors and Media:
Ovid Therapeutics Inc.
Investor Relations & Public Relations
irpr@ovidrx.com

Or

Investors:
Steve Klass
Burns McClellan, Inc.
sklass@burnsmc.com
(212) 213-0006

Media:
Jenn Gordon
Spectrum Science Communications
jgordon@spectrumscience.com
(202) 587-2580