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): March 30, 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 March 30, 2020, Ovid Therapeutics Inc. issued a press release announcing initial data with soticlestat in CDKL5 deficiency disorder and Duplication 15q 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 March 30, 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: March 30, 2020

Ovid Therapeutics Announces Initial Data with Soticlestat in CDKL5 Deficiency Disorder and Dup15q Syndrome

Soticlestat continues to appear to be safe and well-tolerated; the majority of the 11 patients showed a reduction in seizures

All patients that have completed the Phase 2 ARCADE study to date have opted to enroll in the ENDYMION open-label extension study

NEW YORK, March 30, 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 initial data from its ongoing exploratory Phase 2 open-label ARCADE study of soticlestat (OV935/TAK935) in patients with CDKL5 deficiency disorder (CDD) and Dup15q syndrome (Dup15q). CDD and Dup15q are two rare, highly refractory developmental and epileptic encephalopathies (DEE) that have no approved treatment options. These early data demonstrate that soticlestat, a potent, highly selective, first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H), shows a reduction in seizure frequency compared to baseline levels in individual patients.

“This initial data set from the open-label ARCADE study includes the first 11 patients enrolled. This data cut was designed to confirm the safety profile of soticlestat in these patient populations and assess any signals of efficacy. These initial data suggest that soticlestat continues to be safe and well tolerated and appears to reduce seizure frequency in a majority of the individual patients,” said Amit Rakhit, M.D., MBA, President and Chief Medical Officer of Ovid Therapeutics. “These early results are encouraging and are supportive of continuation of the ARCADE study. We are also encouraged that all ARCADE patients that have completed the study to date have opted to roll over into the ENDYMION open-label extension study. We will work closely to evaluate the full data from the ARCADE study, expected in the first quarter of 2021.”

Matthew During, M.D., D.Sc., Chairman of the Company’s Scientific Advisory Board and Visiting Professor of Translational Neuroscience, University of Oxford, commented, “While this initial data includes only a limited number of patients, these results of the ARCADE open-label trial are encouraging and support the safety and tolerability of soticlestat in CDD and Dup15q. More data is needed to assess efficacy, but initial data support the potential of soticlestat to provide a clinical benefit for patients with these ultra-rare and treatment-refractory epilepsy disorders. These initial results support continued recruitment and enrollment into the study.”

Phase 2 ARCADE Study Design and Patient Baseline Demographics

ARCADE is an ongoing, multicenter, open-label, pilot study of soticlestat in patients ages 2 to 55 with refractory epileptic seizures associated with CDD or Dup15q and will enroll up to 30 patients. This study consists of a four- to six-week screening period to establish baseline seizure frequency followed by an eight-week dose optimization period and a 12-week maintenance period. Afterward, patients are offered the chance to continue in Ovid’s open-label extension trial (ENDYMION).

The preliminary data reported today includes a total of 11 patients, five with CDD and six with Dup15q. In the CDD cohort, the median age was 4 years and baseline overall seizure frequency ranged from 10 to 326 per 28 days. In the Dup15q cohort, the median age was 13.5 years and baseline overall seizure frequency ranged from 35 to 630 per 28 days. The majority of these patients were concomitantly

treated with at least two anti-epileptic drugs (AEDs). The most common AEDs taken by the patients were topiramate, clobazam, felbamate, rufinamide and valproate.

Phase 2 ARCADE Study – Initial Efficacy Data

Due to the limited number of patients in this initial data cut, Ovid will provide the median seizure reduction and other endpoints with the full data release expected in the first quarter of 2021. Data from the first 11 patients suggests that soticlestat may reduce seizure frequency compared to baseline levels in individual patients.

In the CDD cohort (n=5), patients exhibited a variety of seizures types including motor (tonic and atonic) and cluster seizures, as well as epileptic spasms.

- One patient showed an improvement of 61% fewer motor seizures during the maintenance phase (75% reduction during the full treatment period) with two consecutive seizure-free 28-day intervals.
- A second patient showed similar improvement with 63% motor seizure reduction during the maintenance phase (30% reduction over the full treatment period).
- A third patient with cluster seizures had a 45% reduction during the maintenance phase (47% reduction over the full treatment period).
- Three patients with epileptic spasms (including two of the three mentioned above) had a 21%, 95% and 100% reduction during the maintenance phase and (29%, 98% and 90% reduction in spasms respectively over the full treatment period).
- One of the five patients did not show a meaningful improvement in any type of seizure reduction. Of interest, this patient had poor treatment compliance (40% compared to an average of 96% for the other ten patients in both cohorts).
- In the three patients that completed the full treatment period at the time of this data cut, motor seizure-free days in two of these patients increased by 37% and 38%, the third patient did not show improvement.

In the Dup15q cohort (n=6), patients also exhibited a variety of seizures types including motor (tonic and atonic), myoclonic and absence seizures.

- In one patient with pure motor seizures (34.8 seizures per 28-day baseline), seizure frequency was reduced by 90% during the 12-week maintenance phase (89% over the full treatment period). This patient also had two 28-day seizure-free periods.
- The other five patients in the Dup15q cohort with mixed seizure types showed preliminary signs of efficacy, as follows:
  - Three patients with myoclonic seizures showed a 60%, 66% and 100% reduction over the maintenance period (and by 74%, 65% and 100% respectively over the full treatment period).
  - Two patients had absence seizures and showed a 78% and 74% reduction in absence seizures during the maintenance phase (74% and 51% reduction over the full treatment period).
- In the five patients that completed the full treatment period at the time of this data cut, motor seizure free days in four of these patients increased by 64%, 159%, 539% and 590%, the fifth patient did not show improvement.

Phase 2 ARCADE Study – Initial Safety Results

Soticlestat was generally well-tolerated in this study and demonstrated a safety profile consistent with the findings of previous studies. The most common adverse events were constipation (n=3; 27%), fatigue (n=2; 18%), nasopharyngitis (n=2; 18%) and seizure (n=2; 18%). Additionally, there were no adverse event-related withdrawals, serious adverse events or deaths reported.

Initial Long-Term Open-Label Extension Data from ARCADE Patients Rolling Over into ENDYMION

All patients that have completed the ARCADE study have enrolled in ENYDMION. The primary objective of ENDYMION is to assess the long-term safety and tolerability of soticlestat over four years of treatment in patients with rare epilepsies and secondarily, to evaluate the effect of soticlestat on seizure frequency over time.

As with the initial ARCADE data, longer-term results from the patients who enrolled in ENDYMION continue to demonstrate a safety profile consistent with previous findings. There was no treatment interruption prior to rollover into ENDYMION and the baseline seizure frequency used in the analysis below is the ARCADE baseline. Six patients from the ARCADE study completed at least 12 weeks of treatment in ENDYMION. Seizure reduction data from this cohort further supports the potential of soticlestat in these highly refractory conditions.

- In the CDD cohort (n=2) one patient had a reduction in overall seizures of 56% during their most recent 12-week interval (24 weeks).
- In the Dup15q cohort (n=4) all four patients had a reduction in overall seizures. Two patients had a reduction of 24% and 96% during their first 12-week interval. The other two patients had a reduction of 50% and 61% during their most recent 12-week interval (48 weeks).
- One CDD patient did not improve.

About CDKL5 Deficiency Disorder and Dup15q Syndrome

Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) and Duplication 15q (Dup15q) syndrome are rare and severe developmental and epileptic encephalopathies (DEE) caused by genetic mutation in the CDKL5 gene on the X chromosome and partial duplication of Chromosome 15, respectively. These mutations are thought (among other effects) to result in excess transmission of glutamate, an excitatory neurotransmitter, that in turn leads to epilepsy and other characteristic neurobehavioral symptoms of CDD and Dup15q syndrome. Despite the availability of medicines for epilepsy generally, there are no approved therapies for CDD and Dup15q syndrome.

About Developmental and Epileptic Encephalopathies (DEE)

The International League Against Epilepsy (ILAE) defines an epileptic encephalopathy as a condition in which "the epileptiform EEG abnormalities themselves are believed to contribute to a progressive disturbance in cerebral function." These epilepsies cause significant morbidities for patients beyond what might be expected from the known underlying pathology alone and can worsen over time. Developmental and epileptic encephalopathies typically present early in life and are often associated with severe cognitive and developmental impairment in addition to frequent treatment-resistant seizures throughout the person's lifetime. These disorders vary in age of onset, developmental outcomes, etiologies, neuropsychological deficits, electroencephalographic (EEG) patterns, seizure types, and prognosis.

Despite the availability of medicines for epilepsy, there are few approved therapies for DEE and for several types there are no approved therapies. 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 (AEDs).

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 and others. The FDA has granted orphan drug designation to soticlestat for the treatment of both Dravet syndrome and Lennox-Gastaut syndrome.

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 (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." 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 related to the global COVID-19 pandemic, 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". 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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