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): September 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** **(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))

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 September 30, 2020, Ovid Therapeutics Inc. (the "Company") issued a press release announcing data from its ARCADE and ENDYMION trials of soticlestat (OV935/TAK-935) in CDKL5 deficiency disorder and Dup15q 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 September 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: September 30, 2020

Ovid Therapeutics Provides Soticlestat (OV935/TAK-935) Results from ARCADE and ENDYMION Studies Showing Seizure Reduction in Rare Epilepsies

- Results from signal-finding, pilot Phase 2 open-label ARCADE study and ENDYMION long-term extension study in CDKL5 deficiency disorder (CDD) and Dup15q syndrome (Dup15q) show seizure frequency reduction over time
- In CDD patients, median motor seizure frequency reduction was 24% in the ARCADE study, increasing to a 50% reduction in ENDYMION long-term extension study
- Clinical Global Impression of Change (CGI-C) and Caregiver Global Impression of Change (Care GI-C) suggest improvements beyond motor seizure frequency reduction in both CDD and Dup15q patients
- Soticlestat was generally well tolerated in both studies and continues to demonstrate a favorable safety profile

NEW YORK, September 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 results from the ARCADE and ENDYMION studies of soticlestat (OV935/TAK-935) in patients with developmental and epileptic encephalopathies (DEEs), or rare epilepsies. The Phase 2 ARCADE study is a signal-finding open-label pilot study of soticlestat in patients with CDKL5 deficiency disorder (CDD) and Dup15q syndrome (Dup15q), two highly refractory rare epilepsies that have no approved treatment options, while ENDYMION is an open-label long-term extension study with soticlestat. All patients who completed the ARCADE study opted to roll over into ENDYMION. Soticlestat is a potent, highly selective, oral, first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H) being developed in collaboration with Takeda Pharmaceutical Company Limited.

Together, data from the ARCADE and ENDYMION studies show seizure frequency reduction over time. In CDD patients (n=12), median motor seizure frequency reduction was 24% during the 12-week maintenance period in the ARCADE study, increasing to a 50% reduction in the ENDYMION long-term extension study in the five CDD patients who reached nine months of continuous treatment. In Dup15q patients (n=8), there was an increase in median motor seizure frequency in the ARCADE study during the 12-week maintenance period; however, longer-term data from the four Dup15q patients who reached nine months of continuous treatment showed a 74% reduction in median motor seizure frequency. Soticlestat was generally well tolerated in both studies and continues to demonstrate a favorable safety profile. Data reported today are consistent with, and build upon, previous findings with soticlestat.

“CDD and Dup15q patients have various seizure types and are on multiple concomitant antiseizure medications per current medical practice, and yet they still lack significant control of their respective seizures,” said Amit Rakhit, M.D., MBA, President and Chief Medical Officer of Ovid Therapeutics. “Data from ARCADE, while a small open-label study, and ENDYMION support previous findings of the early activity of soticlestat and, importantly, the longer-term ENDYMION study shows seizure frequency reduction across multiple rare epilepsies over time. Data from ARCADE and ENDYMION will help inform next development steps for the soticlestat program in CDD and Dup15q, while we prepare to discuss data from our Phase 2 ELEKTRA study in Dravet syndrome and Lennox-Gastaut syndrome with the FDA.”

“Anti-epileptic drugs can lose efficacy over time. Soticlestat may produce acute and long-term antiseizure effects in addition to potential improvements outside of motor seizure frequency reduction as suggested by clinical global impression scales,” said Scott Demarest, M.D., child epileptologist, Assistant Professor of Pediatrics and Neurology at the University of Colorado. “Soticlestat is emerging as a potentially valuable therapeutic option, particularly given its favorable safety profile and potential to provide a durable treatment benefit. Patients with these disorders need more options to manage their treatment-resistant seizures, and collective data from the Phase 2 ELEKTRA, ARCADE and ENDYMION studies warrant further investigation of soticlestat.”

ARCADE is a Phase 2 open-label, signal-finding pilot study designed to inform the potential for future development of soticlestat in CDD and Dup15q. The study enrolled 20 patients, ages 2 to 55 years, with refractory epileptic seizures associated with CDD (n=12) or Dup15q (n=8) and consisted of a four- to six-week screening period to establish baseline seizure frequency, followed by a 20-week treatment period, including an eight-week titration/dose optimization period and a 12-week maintenance period. Patients in the study were allowed to be on one to six concomitant anti-epileptic drugs (AEDs), with the majority of patients concomitantly treated with at least four AEDs, representing a highly refractory patient population. The primary objective of the ARCADE study was to determine percent change from baseline in motor seizure frequency during the 12-week maintenance period. Afterward, patients were offered the chance to continue soticlestat treatment in the ENDYMION open-label extension study, and all patients who completed ARCADE elected to roll over into ENDYMION.

ENDYMION is a multi-center, open-label extension study of soticlestat in any patient who has participated in any previous soticlestat DEE clinical study, including patients with CDD, Dup15q, Dravet syndrome and Lennox-Gastaut syndrome. The primary objective of ENDYMION is to assess the long-term safety and tolerability of soticlestat in patients with DEEs and, secondarily, to evaluate the effect of soticlestat on seizure control over time.

Data from CDKL5 Deficiency Disorder (CDD)
CDD patients exhibited a variety of seizures types, including motor (tonic and atonic) and cluster seizures, as well as epileptic spasms. In CDD patients (n=12), median motor seizure frequency reduction was 14% during the 20-week study period (eight-week dose titration and 12-week maintenance period) and 24% during the 12-week maintenance period (primary objective of the study). In the ARCADE study, two CDD patients experienced a ≥50% to <75% reduction in motor seizures, and one CDD patient experienced a ≥75% reduction in motor seizures during the 20-week study period. All CDD patients rolled over into the ENDYMION open-label extension study and continue to receive soticlestat. Five CDD patients have reached nine months of continuous treatment with soticlestat, achieving a 50% median motor seizure frequency reduction at this time interval. Beyond motor seizures, individual CDD patients also demonstrated improvements in other seizure types, as reported previously.

Overall clinical benefit of treatment was assessed by the Clinical Global Impression of Change (CGI-C; investigator) and Caregiver Global Impression of Change (Care GI-C) scales. 67% of CDD patients were deemed markedly improved with minimal or no adverse events on the CGI-C scale after starting soticlestat treatment. For the Care-GI-C scale, 92% of caregivers reported improvement on soticlestat treatment at the end of the ARCADE study, with 42% reporting much and very much improved. In the ARCADE study CDD cohort, exit interviews from the caregiver also give insight into improvements in verbal and nonverbal communication, alertness/level of engagement, overall quality of daily functioning and caregiver-chosen domains to suggest benefits of soticlestat treatment in domains beyond seizure control.

Data from Dup15q Syndrome
Dup15q patients also exhibited a variety of seizures types, including motor (tonic and atonic), myoclonic and absence seizures. In Dup15q patients (n=8), there was an increase in median motor seizure frequency of 13% during the 20-week study period (eight-week dose titration and 12-week maintenance period) and an increase of 12% during the 12-week maintenance period (primary objective of the study). However, longer-term data from the four Dup15q patients who reached nine months of continuous treatment with soticlestat in ENDYMION showed a 74% reduction in median motor seizure frequency. Individual Dup15 patients demonstrated improvements in other seizure types, as reported previously.

In addition, 38% of Dup15q patients were deemed markedly improved with minimal or no adverse events on the CGI-C scale after starting soticlestat treatment. For the Care-GI-C scale, 50% (in 4/8 patients) of caregivers reported improvement on soticlestat treatment at the end of the ARCADE study. Exit interviews from the caregiver for the ARCADE study Dup15 cohort also show similar improvements to the CDD patients in the study.

Safety and Tolerability Profile of Soticlestat
Soticlestat was generally well tolerated in the ARCADE study and demonstrated a safety profile consistent with the findings of previous studies with no new safety signals identified. The most common adverse events were constipation (n=4/20, 20%), rash (n=3/20, 15%) and seizure (n=3/20, 15%). Additionally, there were no serious adverse events considered related to study drug or deaths reported. As with the initial ARCADE data, longer-term results from the ARCADE patients who enrolled in ENDYMION continue to demonstrate a safety profile consistent with previous findings.

In the ARCADE study, a reduction of plasma 24HC levels was observed with soticlestat treatment, and plasma 24HC continues to show potential as a biomarker of pharmacodynamic activity.

Detailed efficacy and safety data is included in the Company's updated corporate presentation, which can be accessed via the presentations and events section of Ovid's website.

About Soticlestat (OV935/TAK-935)
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.

Ovid and Takeda recently announced positive topline results from the randomized Phase 2 ELEKTRA study of soticlestat in children with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS).

Takeda and Ovid are sharing in the development and commercialization costs of soticlestat on a 50/50 basis, and if successful, the companies will share in the profits on a 50/50 basis. Takeda will be responsible for commercialization in Japan and has the option to be responsible for commercialization in other countries in Asia and other selected countries. Ovid will be responsible for clinical development activities and commercialization of soticlestat in the United States, Europe, Canada and Israel. Under the terms of the agreement, Takeda received equity in Ovid and may be eligible to receive certain milestone payments based on the advancement of soticlestat.

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 (DEEs) caused by genetic mutations 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 (DEEs)
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 DEEs 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 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 (DEEs). For more information on Ovid, please visit www.ovidrx.com.

Forward-Looking Statements
This press release includes certain disclosures that contain “forward-looking statements,” including, without limitation, statements regarding the potential benefits, clinical and regulatory development and commercialization of soticlestat, the potential value and benefits of the collaboration with Takeda, the likelihood that data will support future development, and the association of data with treatment outcomes. You can identify forward-looking statements because they contain words such as “will,” “appears,” “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 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.” Such risks may be amplified by the COVID-19 pandemic and its potential impact on Ovid’s business and the global economy. 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:
Dan Budwick
1AB
dan@1abmedia.com