# 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 11, 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**<br>**New York, New York**<br>**(Address of Principal Executive Offices)** | 10036<br>**(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 2.02. Results of Operations and Financial Condition.**

On March 11, 2020, Ovid Therapeutics Inc. (the "Company") issued a press release announcing Fourth Quarter and Full Year 2019 Financial Results. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibit

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated March 11, 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 11, 2020

# Ovid Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results, Provides Corporate Update for 2020

- Multiple clinical data readouts across Ovid's pipeline expected in 2020
- Completed financings in the fourth quarter strengthening the balance sheet

**NEW YORK, March 11, 2020** -- Ovid Therapeutics Inc. (NASDAQ: OVID), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological diseases, today reported financial results for the fourth quarter and full year ended December 31, 2019 and provided an overview of the Company's recent progress and key clinical readouts anticipated in 2020.

"We are entering a transformational period for Ovid," said Jeremy Levin, DPhil, MB, BChir, Chairman and Chief Executive Officer of Ovid Therapeutics. "2020 is a year where the team at Ovid looks to deliver on the hard work of the last several years. In anticipation of these important clinical readouts, during the fourth quarter of 2019 we raised approximately $56.0 million, providing us with sufficient capital to achieve all of these clinical data points. If we are successful, we have the potential to change the practice of medicine in one area and drive exciting new changes in a second."

Amit Rakhit, M.D. MBA, President and Chief Medical Officer, said, "We have made significant clinical progress across the pipeline during 2019, which leads us to an eventful 2020 with multiple clinical data readouts expected this year. This includes initial data from the ongoing open-label Phase 2 ARCADE study in CDKL5 deficiency disorder and Dup15q syndrome by the end of the first quarter of 2020. In addition, early in the second quarter of 2020, we will have data from our signal-finding Phase 2 ROCKET trial in Fragile X syndrome along with SKYROCKET, our non-interventional trial in Fragile X syndrome. Also, we completed enrollment significantly ahead of schedule in our placebo-controlled Phase 2 ELEKTRA trial in children with Dravet syndrome and Lennox-Gastaut syndrome, and as a result, we now expect data to be available in the third quarter of 2020. We are also pleased to report that all patients who have completed the ELEKTRA and ARCADE trials have rolled over into our ENDYMION open-label extension study."

Dr. Rakhit continued, "We are also very excited to see the results of our pivotal Phase 3 NEPTUNE trial in Angelman syndrome. Patient interest in our trial has been strong, and we are on track for clinical data mid-year. There are currently no approved therapies for Angelman syndrome. Achieving a clinically significant improvement in the NEPTUNE trial will indicate that OV101 has the potential to provide these patients and their families with a much-needed treatment, one for which the community has been waiting since the condition was first described over 50 years ago. If successful, this may serve as a basis for an oral once-a-day treatment option for people with Angelman syndrome."

*OV101 (gaboxadol) for Angelman Syndrome and Fragile X Syndrome*

- Ovid continues to enroll patients in the pivotal Phase 3 NEPTUNE trial in Angelman syndrome. NEPTUNE is a Phase 3, randomized, double-blind, placebo-controlled pivotal trial to evaluate the efficacy and safety of gaboxadol in children ages 4 to 12 with a confirmed diagnosis of Angelman syndrome. The primary endpoint, CGI-I-AS, is an objective clinician-assessed measure of the totality of a patient's change in a number of key affected areas over the duration of the clinical trial. NEPTUNE, if positive, will be part of a broad data set intended to support registrational filings for gaboxadol in the U.S. and the rest of the world. We expect to release topline data from NEPTUNE mid-year 2020.

- Ovid expects results from the Phase 2 ROCKET trial and the SKYROCKET trial in Fragile X syndrome early in the second quarter of 2020. There are no approved treatments for Fragile X syndrome.

    - 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 dose arms. 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). If positive, the data from ROCKET, along with data from SKYROCKET, will inform next steps in the clinical path for gaboxadol in Fragile X syndrome.

    - SKYROCKET 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, gain deeper understanding of placebo effects in this disorder and provide comparative data on the benefit offered by the standard of care.

*OV935/TAK935 (soticlestat) for Rare Developmental and Epileptic Encephalopathies (DEE)*

- The ARCADE trial is enrolling patients with CDKL5 deficiency disorder (CDD) and Dup15q syndrome, both of which have no approved treatments. Initial data from this trial are expected before the end of the first quarter 2020.

    - ARCADE is a multicenter, open-label pilot study that will evaluate the treatment of soticlestat in patients ages 2 to 55 with refractory motor seizures associated with CDD or Dup15q syndrome. This study consists of a four- to six-week screening period to establish baseline seizure frequency followed by a 20-week treatment period. The primary endpoint is the percent change in motor seizure frequency in patients treated with soticlestat by disorder. This initial data set may inform us on the development path forward. Full results from the Phase 2 ARCADE trial are expected in early 2021.

- ARCADE open-label long-term cohort: Once patients complete the ARCADE trial, they are offered the chance to immediately enroll in the open-label ENDYMION trial. To date, all patients who have finished the ARCADE trial have opted to enroll in the ENDYMION trial. Along with the initial ARCADE data in first quarter of 2020, Ovid plans to report longer-term data from the ARCADE patients who have enrolled in the ENDYMION trial.

- The ELEKTRA trial has completed enrollment in patients with Dravet syndrome and Lennox-Gastaut syndrome (LGS). Topline results are expected in the third quarter of 2020.

    - ELEKTRA is an international, multicenter, randomized, double-blind, placebo-controlled study that will evaluate the treatment of soticlestat in pediatric patients ages 2 to 17 with seizures associated with Dravet syndrome (convulsive seizures) or LGS (drop seizures). The study is fully enrolled and was enrolled substantially ahead of schedule. The study consists of a four- to six-week screening period to establish baseline seizure frequency followed by a 20-week treatment period. The primary endpoint is the percent change from baseline in seizure frequency in patients treated with soticlestat compared to placebo.

    - ELEKTRA open-label long-term cohort: Once patients complete the ELEKTRA trial, they are offered the chance to immediately enroll in the open-label ENDYMION trial. All patients who have finished the ELEKTRA trial have opted to enroll in the ENDYMION trial. Ovid plans to report longer-term data from ENDYMION in conjunction with the results of the Phase 2 ELEKTRA trial expected in the third quarter of 2020.

    - ENDYMION open-label long-term trial for all patients who previously participated in a trial of soticlestat: 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. Ovid anticipates that the longer-term ENDYMION data to be reported with the results from ELEKTRA will also include patients from Ovid's Phase 1b/2a adult clinical trial in DEE and patients from the ARCADE trial.

*Summary of Anticipated Clinical Data Readouts*

| Product Candidate | Trial | Condition or Disease | Phase of Clinical Trial | Expected Timing o Release |
|---|---|---|---|---|
| Soticlestat | ARCADE (Initial Data) | CDD or Dup15q syndrome | Phase 2 | End of 1Q 2020 |
| Soticlestat | ENDYMION – ARCADE Cohort | CDD or Dup15q syndrome | Open-label Extension | End of 1Q 2020 (concurrent with ARCADE) |
| Gaboxadol | ROCKET | Fragile X | Phase 2 | Early 2Q 2020 |
| Gaboxadol | SKYROCKET | Fragile X | Non-treatment, observational | Early 2Q 2020 |
| Gaboxadol | NEPTUNE | Angelman syndrome | Phase 3 | Mid-2020 |
| Soticlestat | ELEKTRA | Dravet syndrome or LGS | Phase 2 | 3Q of 2020 |
| Soticlestat | ENDYMION – All Patients | CDD, Dup15q syndrome, Dravet syndrome, LGS, other DEEs | Open-label Extension | 3Q of 2020 (concu with ELEKTRA) |
| Soticlestat | ARCADE (Full Data) | CDD or Dup15q syndrome | Phase 2 | Early 2021 |

**Fourth Quarter 2019 Corporate Update**

- Raised approximately $56.0 million of net proceeds from the October public offering and from the sales of common stock through Ovid's At-The-Market (ATM) program, strengthening the balance sheet as we enter a year of important clinical milestones.

- Strengthened the leadership team with the appointment of Jason Tardio as Chief Commercial Officer as the Company prepares for its next stage of growth.

**Fourth Quarter and Year Ended December 31, 2019 Financial Results**

- As of December 31, 2019, cash, cash equivalents and short-term investments totaled $76.7 million, including net proceeds of $33.7 million from a public equity offering in October 2019, including the exercise of the underwriters' option to purchase additional shares, and after deducting the underwriting discounts and commissions and other offering expenses. This cash balance also increased due to $22.3 million in net proceeds generated from the sale of common stock under Ovid's ATM facility during the fourth quarter of 2019.

- Research and development expenses were $12.1 million and $42.2 million for the fourth quarter and year ended December 31, 2019, respectively, as compared to $8.6 million and $33.8 million for the same periods in 2018. The increase for the year ended December 31, 2019, was primarily due to an increase in development activities related to our ongoing development programs.

- General and administrative expenses were $5.2 million and $19.3 million for the fourth quarter and year ended December 31, 2019, respectively, as compared to $4.5 million and $19.1 million for the same periods in 2018. The difference was primarily due to an increase in legal and professional fees, offset by decreases in general office expenses, payroll and payroll-related expenses.

- The Company reported a net loss of $17.0 million, or basic and diluted net loss per share attributable to common stockholders of $0.35, for the fourth quarter of 2019, as compared to a net loss of $12.9 million, or basic and diluted net loss per share attributable to common stockholders of $0.52, for the same period in 2018. The Company reported a net loss of $60.5 million, or basic and diluted net loss per share attributable to common stockholders of $1.54, compared to a net loss of $52.0 million, or basic and diluted net loss per share attributable to common stockholders of $2.11, for the year ended December 31, 2018.

**About OV101 (gaboxadol)**
Gaboxadol is believed to be the only delta (δ)-selective GABAA 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 GABAA 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 GABAA 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. 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 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 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.

**Condensed Consolidated Statements of Operations**
**(Unaudited)**

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Operating expenses: | | | | |
| Research and development | $ 12,105,209 | $ 8,621,585 | $ 42,157,641 | $ 33,790,031 |
| General and administrative | 5,162,720 | 4,504,711 | 19,251,826 | 19,141,652 |
| Total operating expenses | 17,267,929 | 13,126,296 | 61,409,467 | 52,931,683 |
| Loss from operations | (17,267,929) | (13,126,296) | (61,409,467) | (52,931,683) |
| Interest income | 298,720 | 226,364 | 948,224 | 952,073 |
| Net loss and comprehensive loss | $(16,969,209) | $(12,899,932) | $(60,461,243) | $(51,979,610) |
| Net loss attributable to common stockholders | $(16,969,209) | $(12,899,932) | $(60,461,243) | $(51,979,610) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.35) | $ (0.52) | $ (1.54) | $ (2.11) |
| Weighted-average common shares outstanding basic and diluted | 49,142,504 | 24,635,038 | 39,217,223 | 24,631,011 |

**Selected Condensed Balance Sheet Data**
**(Unaudited)**

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 76,739,113 | $ 41,500,652 |
| Working capital[1] | $ 69,279,584 | $ 35,423,690 |
| Total assets | $ 80,843,731 | $ 47,649,602 |
| Total stockholders' equity | $ 70,023,561 | $ 38,805,145 |

[1]Working capital defined as current assets less current liabilities

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