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 15, 2021

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 2.02. Results of Operations and Financial Condition.

On March 15, 2021, Ovid Therapeutics Inc. (the "Company") issued a press release announcing Fourth Quarter and Full Year 2020 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 15, 2021

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 15, 2021

Ovid Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results, Provides Corporate Update for 2021

- Announced signing of transaction transferring Ovid's 50% of global rights to develop and commercialize soticlestat (TAK-935/OV935) to Takeda, under which Ovid is eligible to receive up to $856 million in payments, including an upfront payment of $196 million at closing
- Two pivotal Phase 3 trials of soticlestat in Dravet syndrome and Lennox-Gastaut syndrome on track to commence in the second quarter of 2021, and upon the successful closing of the transaction, to be fully funded and conducted by Takeda
- Cash balance, upon successful closing of the transaction, provides resources to develop and continue to build an exciting pipeline and platform of technologies

NEW YORK, March 15, 2021 – Ovid Therapeutics Inc. (NASDAQ: OVID) ("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, 2020 and provided an overview of the Company's recent progress.

"This new agreement with Takeda strategically positions Ovid, upon closing, to advance our next generation neuroscience pipeline, while demonstrating the value we helped to create for soticlestat by bringing it to the initiation of two pivotal Phase 3 trials," said Jeremy M. Levin, DPhil, MB, BChir, Chairman and Chief Executive Officer of Ovid Therapeutics. "Importantly, we believe this is a positive outcome for patients, potentially accelerating soticlestat's clinical development with the potential to make this new treatment commercially available in 2024. We are excited for next steps both for this asset and for our pipeline, as we work to file three INDs over the next three years and in tandem pursue an active business development initiative."

Corporate Update

- In March 2021, Ovid announced that it entered into an agreement with Takeda Pharmaceutical Company Limited ("Takeda") under which Takeda will secure global rights at closing from Ovid to develop and commercialize the investigational medicine soticlestat (TAK-935/OV935) for the treatment of developmental and epileptic encephalopathies (the "transaction"), including Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS). On closing, Takeda will assume sole responsibility for further worldwide development and commercialization, and Ovid will no longer have any financial obligation to Takeda. Ovid will receive an upfront payment of $196 million at closing and is eligible to receive up to an additional $660 million upon achieving development, regulatory and sales milestones. In addition, if soticlestat achieves regulatory approval, Ovid will receive tiered royalties beginning in the low double-digits and up to 20 percent on net sales of soticlestat, subject to standard reductions in certain circumstances. The new agreement is expected to close by end of March 2021

subject to the satisfaction of customary closing conditions, including review by the appropriate regulatory agencies under the Hart-Scott-Rodino Act.

- Upon closing of the transaction with Takeda, all of Ovid's financial obligations to Takeda and the soticlestat program will be terminated resulting in an estimated savings of at least $250 million. Ovid will not incur any additional expenditures relating to the development and commercialization of soticlestat.

- As a result of the transaction with Takeda, Ovid expects to reduce its cash spend significantly at closing. The Company anticipates quarterly operating expenses, excluding non-cash expenses, to be in the range of $8 million to $10 million, following the closing of the transaction with Takeda.

Pipeline Update

- **OV101 (gaboxadol):** In December 2020, Ovid announced that topline results from the Phase 3 NEPTUNE clinical trial of OV101 (gaboxadol) for the treatment of Angelman syndrome did not achieve the primary endpoint. Ovid is completing a full analysis of the study along with the open label extension study (ELARA), and will discuss these results with the U.S. Food and Drug Administration (FDA).

- **OV935/TAK935 (soticlestat):** The two pivotal Phase 3 studies for both DS and LGS are currently on track to commence in the second quarter of 2021, and upon closing of the transaction will be fully operated and funded by Takeda. If successful, soticlestat could be commercially available as early as 2024.

- Over the past 18 months, Ovid has assembled a robust early-stage pipeline and plans to submit three IND applications over the next three years starting next year.

    - **OV329:** A highly selective small molecule GABA aminotransferase (GABA-AT) inhibitor that will be developed for the treatment of seizures associated with tuberous sclerosis complex and infantile spasms. IND-enabling studies are anticipated in 2021 and the Company plans to submit an IND in the first half of 2022.

    - **OV882:** This asset explores short hairpin RNA and its ability to interfere with UBE3A antisense that blocks UBE3A gene expression in neurons. In partnership with the University of Connecticut, Ovid is exploring the use of OV882 as a noncoding RNA construct that reduces expression of UBE3a-antisense and restores UBE3A expression via the paternal gene. Based on encouraging discovery data to date, the Company expects to select and name a development candidate by the end of 2021 and enter IND-enabling studies.

    - **OV815:** Currently in target validation, OV815 is a gene-modulation approach focused on the kinesin family of proteins initially targeting KIF1A. This asset is part of a collaboration with the Genomics Center at Columbia University.

Fourth Quarter and Year Ended December 31, 2020 Financial Results

- As of December 31, 2020, cash, cash equivalents and short-term investments totaled $72.0 million, including the receipt of a $5.0 million milestone payment from Angelini Pharma Rare Diseases AG

("Angelini") during the fourth quarter, for the completion of the technology transfer and compound delivery of OV101 in Angelman syndrome in accordance with Ovid's license agreement with Angelini.

- Revenue of $5.7 million was recognized during the fourth quarter of 2020, as compared to zero for the same period in 2020. Revenue of $12.6 million was recognized for the full year 2020, as compared to zero for the same period in 2020. Revenue recognized during 2020 was related to Ovid's license agreement with Angelini.

- Research and development expenses were $16.9 million and $63.4 million for the fourth quarter and year ended December 31, 2020, respectively, as compared to $12.1 million and $42.2 million for the same periods in 2019. The increase for the year ended December 31, 2020, was primarily due to an increase in development activities related to our OV101 and OV935 development programs.

- General and administrative expenses were $10.4 million and $30.6 million for the fourth quarter and year ended December 31, 2020, respectively, as compared to $5.2 million and $19.3 million for the same periods in 2019. The difference was primarily due to increases in legal fees, compliance and pre-commercialization expenses and professional fees.

- The Company reported a net loss of $22.0 million, or basic and diluted net loss per share attributable to common stockholders of $0.34, for the fourth quarter of 2020, as compared to a net loss of $17.0 million, or basic and diluted net loss per share attributable to common stockholders of $0.35, for the same period in 2019. The Company reported a net loss of $81.0 million, or basic and diluted net loss per share attributable to common stockholders of $1.39 for the year ended December 31, 2020, compared to a net loss of $60.5 million, or basic and diluted net loss per share attributable to common stockholders of $1.54, for the year ended December 31, 2019.

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. We believe these disorders represent an attractive area for drug development as the understanding of the underlying biology has grown meaningfully over the last few years and today represents a substantial opportunity medically and commercially. Based on recent scientific advances in genetics and the biological pathways of the brain, we aim to identify, discover and acquire novel compounds for the treatment of rare neurological disorders. We have built a deep knowledge of such disorders, how to treat them and how to develop the clinically meaningful endpoints required for development of a compound in these disorders. As a result of this knowledge, Ovid has developed a robust pipeline of first-in-class compounds and programs. We continue to execute on our strategy to build this pipeline by discovering, in-licensing and collaborating with leading biopharmaceutical companies and academic institutions. These pipeline programs include programs targeting rare epilepsies, Angelman syndrome and Fragile X syndrome, as well as early-stage programs into other monogenetic disorders. Ovid's most advanced pipeline programs include OV935 (soticlestat) in collaboration with Takeda and OV101 a δ-selective $GABA_A$ receptor agonist. Ovid's emerging pipeline programs include OV329, a small molecule GABA aminotransferase inhibitor for seizures associated with Tuberous Sclerosis Complex and Infantile Spasms; OV882, a short hairpin RNA therapy approach for Angelman syndrome; OV815, a genetic therapy approach for KIF1A associated neurological disorder; and other non-disclosed researched targets. 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 and Ovid’s other programs and potential programs, the closing of the Royalty, License and Termination Agreement and the potential value, benefits, and outcome of the collaboration with Takeda. 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, 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, and the ability to commercialize soticlestat. 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.

Condensed Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended December 31, 2020	For the Three Months Ended December 31, 2019	For the Year En 2
Revenue:			
License revenue	$ 5,703,187	$ -	
Operating expenses:			
Research and development	$ 16,883,784	$ 12,105,209	
General and administrative	10,410,644	5,162,720	
Total operating expenses	27,294,428	17,267,929	
Loss from operations	(27,294,428)	(17,267,929)	
Other (expense) income, net	(438,260)	298,720	
Net loss	$ (22,029,501)	$ (16,969,209)	
Net loss attributable to common stockholders	$ (22,029,501)	$ (16,969,209)	
Net loss per share attributable to common stockholders, basic and diluted	$ (0.34)	$ (0.35)	
Weighted-average common shares outstanding basic and diluted	64,004,719	49,142,504	

Selected Condensed Balance Sheet Data
(Unaudited)

	December 31 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 72,033,930	$ 76,739,113
Working capital[1]	52,780,426	69,279,584
Total Assets	75,925,518	80,843,731
Total stockholder's equity	43,631,656	70,023,561

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

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