

**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): May 13, 2021

OVID THERAPEUTICS INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38085
(Commission File Number)

46-5270895
(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 2.02. Results of Operations and Financial Condition.

On May 13, 2021, Ovid Therapeutics Inc. (the “Company”) issued a press release announcing first quarter 2021 financial results and provides a corporate update. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 13, 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: May 13, 2021



Ovid Therapeutics Reports First Quarter 2021 Financial Results and Provides Corporate Update

- Closed royalty, license and termination agreement with Takeda for soticlestat; Ovid Therapeutics received an upfront payment of \$196.0 million and is eligible to receive up to \$660.0 million in additional milestone payments, plus tiered double-digit royalties, up to 20%, on sales if soticlestat is commercialized
- Ending Q1'21 cash and cash equivalents balance of \$233.1 million and reduced cash burn supports prioritization of resources to advance robust early-stage neuroscience pipeline and explore full ecosystem of complementary external innovation
- Company is actively pursuing business development opportunities to advance its early-stage neuroscience pipeline and is planning to evaluate clinical stage assets that support its mission to bring innovative therapies to rare neurological disorders
- Appointed MIT Professor Robert S. Langer, Sc.D. as the new Chair of its Scientific Advisory Board

NEW YORK, May 13, 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 quarter ended March 31, 2021 and provided an overview of the Company’s recent progress.

“During the first quarter of 2021, Ovid strengthened its balance sheet, focused its resources, advanced its current programs, and began to explore assets that will complement this next-generation neurosciences pipeline,” said Jeremy M. Levin, DPhil, MB, BChir, Chairman and Chief Executive Officer of Ovid Therapeutics. “Having closed the agreement with Takeda in March, and with the recent appointment of Dr. Robert Langer as Chair of the Scientific Advisory Board, we are adequately capitalized and have in place a validated world-class leadership team to drive forward our mission to impact rare neurological diseases.”

Corporate Update

- In late March, Ovid announced the closing of the Royalty, License and Termination Agreement under which Takeda Pharmaceuticals secured global rights from Ovid to develop and commercialize the investigational medicine soticlestat for the treatment of developmental and epileptic encephalopathies, including Dravet syndrome and Lennox-Gastaut syndrome. At closing, Ovid received an upfront payment of \$196.0 million and is eligible to receive up to an additional \$660.0 million upon achieving development, regulatory and sales milestones. In addition, Ovid is eligible to receive tiered double-digit royalties, up to 20%, on sales of soticlestat, if approved and commercialized.
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- On March 31, 2021, the license and collaboration agreement between Angelini Pharma and the Company was terminated. As such, the Company has been released from its performance obligations and will not be entitled to any future milestone payments under the license and collaboration agreement.
- Ovid has appointed Professor Robert S. Langer, Sc.D. as the Chair of its Scientific Advisory Board to help guide Ovid's strategy to tackle opportunities and scientific questions underlying disorders in the brain. Dr. Langer will play a pivotal role as Ovid expands its thought leadership on its Scientific Advisory Board and develops its pipeline of rare neurology programs and enabling technologies.
- The Company reiterates previous guidance of quarterly operating expenses, excluding non-cash and non-recurring expenses, of between \$8.0 million and \$10.0 million beginning in the second quarter of 2021.

Pipeline Update

- **OV101:** In April, Ovid provided an update on its OV101 program and the reallocation of resources to prioritize the development of its early-stage pipeline including OV329, OV882, and OV815. As part of the restructuring of resources, Ovid will discontinue development of OV101 (gaboxadol), a delta (δ)-selective GABAA receptor agonist, in Angelman syndrome. Furthermore, Ovid does not plan to initiate further clinical studies of OV101 in Fragile X syndrome.
- **Soticlestat:** Two pivotal Phase 3 studies for Dravet syndrome and Lennox-Gastaut syndrome, operated and funded by Takeda, are currently expected to commence in mid-2021. If successful, the Company estimates that soticlestat could be commercially available as early as 2024.

First Quarter 2021 Financial Results

- Revenue of \$208.4 million was recognized during the first quarter of 2021, as compared to zero for the same period in 2020. Revenue recognition was in relation to the receipt of the one-time upfront payment of \$196.0 million pursuant to Ovid's agreement with Takeda, and \$12.4 million recognized in connection with the termination of the license and collaboration agreement with Angelini Pharma.
 - Research and development expenses were \$16.2 million for the quarter ended March 31, 2021, as compared \$14.6 million for the same period in 2020. The increase of \$1.6 million included a decrease in preclinical and development expenses for the clinical studies of OV101 and an increase in Takeda collaboration expenses related to soticlestat.
 - General and administrative expenses were \$15.6 million for the quarter ended March 31, 2021, as compared to \$5.7 million for the same period in 2020. The increase of \$9.9 million was primarily due to an increase in legal fees and professional fees of \$8.8 million, which includes \$8.2 million of one-time fees related to the Takeda License and Termination Agreement.
 - Net income was \$176.0 million for the quarter ended March 31, 2021 resulting in basic net income per share of \$2.55 and diluted net income per share of \$2.53. Net loss was \$20.0 million for the quarter ended March 31, 2020, resulting in basic and diluted net loss per share of \$0.37. Net income for the first quarter ended March 31, 2021 was attributable to a one-time upfront payment of \$196.0
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million pursuant to Ovid's agreement with Takeda, and \$12.4 million recognized in connection with the termination of the license and collaboration agreement with Angelini Pharma.

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. We continue to execute on our strategy to build this pipeline by discovering, in-licensing and collaborating with leading biopharmaceutical companies and academic institutions. 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 research targets. Additionally, Ovid maintains a significant financial interest in a program directed to the exploitation of soticlestat, for which Takeda is responsible for the global development and commercialization, if soticlestat is successfully developed and commercialized. Two phase 3 trials for soticlestat in Dravet syndrome and Lennox-Gastaut syndrome are expected to begin in mid-2021.

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 development of Ovid's pipeline, the clinical and regulatory development and commercialization of soticlestat, the potential value and benefits of the Royalty, License and Termination Agreement with Takeda, Ovid's expectations regarding its operating expenses, and use of its cash, cash equivalents and short-term investments including to develop the Company's pipeline. 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, Ovid's ability to discover and successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize its current and future drug candidates in a timely manner, Takeda's ability to successfully complete clinical development of, obtain regulatory approval for and, if approved, successfully commercialize soticlestat, uncertainties in the development and regulatory approval processes, and the fact that initial data from pre-clinical and clinical trials may not be indicative, and are not guarantees, of the final results of the 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.

Condensed Consolidated Statement of Operations
(unaudited)

	For The Three Months Ended March 31, 2021	For The Three Months Ended March 31, 2020
Revenue:		
License and other revenue	\$ 12,382,779	\$ -
License revenue - related party	196,000,000	-
Total revenue	208,382,779	-
Operating expenses:		
Research and development	\$ 16,248,909	\$ 14,625,367
General and administrative	15,576,554	5,669,019
Total operating expenses	<u>31,825,463</u>	<u>20,294,386</u>
Income (loss) from operations	176,557,316	(20,294,386)
Other (expenses) income, net	(49,732)	264,296
Income (loss) before provision for income taxes	176,507,584	(20,030,090)
Provision for income taxes	500,277	-
Net income (loss)	<u>\$ 176,007,307</u>	<u>\$ (20,030,090)</u>
Net income (loss) per share, basic	<u>\$ 2.55</u>	<u>\$ (0.37)</u>
Net income (loss) per share, diluted	<u>\$ 2.53</u>	<u>\$ (0.37)</u>
Weighted-average common shares outstanding, basic	<u>66,088,592</u>	<u>54,715,610</u>
Weighted-average common shares outstanding, diluted	<u>66,578,377</u>	<u>54,715,610</u>

Selected Condensed Balance Sheet
(Unaudited)

	March 31, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	\$ 233,051,160	\$ 72,033,930
Working capital ¹	220,315,960	52,780,426
Total Assets	237,456,030	75,925,518
Total stockholder's equity	221,109,940	43,631,656

¹Working capital defined as current assets less current liabilities

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