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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 10, 2022

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 May 10, 2022, Ovid Therapeutics Inc. (the "Company") issued a press release announcing First Quarter 2022 Financial Results and Corporate Highlights. 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 May 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 10, 2022

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Ovid Therapeutics Reports First Quarter 2022 Financial Results and Corporate Highlights

- Ovid anticipates filing an investigational new drug application (IND) for OV329, a potent GABA aminotransferase inhibitor, and initiating Phase 1 trials in the fourth quarter of 2022

- Data supporting OV329 in rare and treatment-resistant epilepsies expected to be presented at the upcoming EILAT XVI and Epilepsy Foundation Pipeline conferences

- Entered into an agreement with Tufts University under the direction of Professor Stephen Moss, a recognized leader in epilepsy research, to support advancement of the pipeline

- Multi-year cash and cash equivalents expected to support the progression of the current pipeline of differentiated epilepsy programs into 2025

NEW YORK, May 10, 2022 -- Ovid Therapeutics Inc. (NASDAQ: OVID), a biopharmaceutical company committed to developing medicines designed to conquer epilepsies and meaningfully improve the lives of people affected by brain disorders, today reported financial results and corporate highlights for the first quarter ended March 31, 2022.

“Ovid is focused on propelling our pipeline of potential medicines with novel mechanisms of action for epilepsies and seizures,” said Jeremy M. Levin, D. Phil, MB BChir, Chairman and Chief Executive Officer of Ovid. “We are on track to submit an IND for OV329, a novel GABA aminotransferase inhibitor, for the treatment of epilepsies this year. With our strong balance sheet and experienced team, we believe we have the resources, focus and knowledge to drive our current programs forward and potentially augment them with additional candidates and technologies through business development."

2022 Corporate Highlights & Anticipated Milestones

- **Ovid expects to file an IND for OV329 and initiate Phase 1 trials in the fourth quarter of 2022.** OV329 is a potent GABA aminotransferase inhibitor being studied for the treatment of rare and treatment-resistant forms of epilepsy and seizures, such as tuberous sclerosis complex, infantile spasms and focal seizures.

- **Data supporting the preclinical efficacy and safety profile of OV329 are expected to be presented at epilepsy research meetings in the second quarter of 2022.** Ovid intends to

present preclinical data on OV329 at the EILAT XVI Conference on New Antiepileptic Drugs and Devices in May and the Epilepsy Foundation Pipeline Conference in June.

- **Ovid announced its focus on the therapeutic area of epilepsy**. In March 2022, Ovid reshaped its organizational footprint to align with its focus on epilepsies and direct its resources on its internal candidates for seizures as well as those acquired through business development, such as the library of KCC2 activators it in-licensed last year. As part of the changes, Meg Alexander was appointed to a newly created position, Chief Corporate Affairs Officer from her prior role as Head of Communications. The role consolidates and unites Ovid's engagement strategy across its key stakeholders including community engagement, patient advocacy, investor relations and government affairs.

- **The Company announced its financial strategy and expects its cash and cash equivalents to support advancement of its current epilepsy programs into 2025.**

- **Ovid entered into an agreement with Tufts University under the direction of Professor Stephen Moss.** Dr. Moss, his lab, and team are recognized leaders in epilepsy research and will support the translation and development of Ovid candidates, including OV350, Ovid's direct KCC2 transporter activator candidate.

- **Soticlestat continues to be evaluated by Takeda in two pivotal Phase 3 trials for Lennox Gastaut and Dravet syndromes.** Ovid out-licensed soticlestat to Takeda and is eligible to receive regulatory and commercial milestone payments, as well as royalties on global sales of soticlestat, if it is approved and commercialized.

First Quarter 2022 Financial Results

- Cash and cash equivalents as of March 31, 2022 was $166.7 million.
- Revenue for the first quarter ended March 31, 2022 was $1.4 million, as compared to $208.4 million for the same period in 2021. Revenue recognized for the first quarter ended March 31, 2022 was associated with licensing transactions with Marinus Pharmaceuticals, Inc. and Healx, Ltd. Revenue recognized for the first quarter ended March 31, 2021 was associated with licensing transactions with Takeda Pharmaceuticals (Takeda) and Angelini Pharma, Inc. (Angelini Pharma).
- Research and development expenses were $7.8 million for the quarter ended March 31, 2022, as compared to $16.2 million for the same period in 2021. The decrease of $8.4 million was primarily due to the decision to discontinue the clinical study of OV101 in Angelman syndrome and Fragile X syndrome, and the termination of the Takeda Collaboration Agreement for OV935. The decrease was offset by a payroll and payroll-related expense increase of $1.0 million, which was primarily related to severance pay recognized during the period.
- General and administrative expenses were $9.9 million for the quarter ended March 31, 2022, as compared to $15.6 million for the same period. Expenses decreased by $5.7 million. This

was primarily due to a $7.2 million decrease in legal, professional, and advisory fees that were related to the execution of the Takeda License and Termination Agreement. Partially offsetting these decreases were payroll and payroll-related expenses, which increased by $1.0 million, and were primarily related to severance pay recognized during the period.

- The Company reported net loss of approximately $16.1 million, or basic and diluted net loss per share attributable to common stockholders of $0.23 for the quarter ended March 31, 2022. Net income was $176.0 million for the same period in 2021, resulting in basic net income per share of $2.55 and diluted net income per share of $2.53. Net income for the three months ended March 31, 2021, was attributable to a one-time upfront payment of $196.0 million (pre-tax) pursuant to the Takeda License and Termination Agreement, and $12.4 million recognized in connection with the termination of the license and collaboration agreement with Angelini Pharma.
- Operating expenses were $17.7 million for the quarter ended March 31, 2022, and non-GAAP adjusted operating expenses (which exclude non-recurring expenses and non-cash expenses; see table on Reconciliation of Non-GAAP Expenses) were $14.2 million for the quarter. See "Non-GAAP Financial Measures" below for a discussion of non-GAAP adjusted operating expenses.

Non-GAAP Financial Measures

This press release presents non-GAAP adjusted operating expenses on a historical and projected basis. For the period presented, non-GAAP adjusted operating expenses exclude from operating expenses, as calculated and presented in accordance with GAAP, the following non-recurring, non-cash and non-routine items: wind down of OV101 clinical costs; stock-based compensation, and severance fees. Non-GAAP adjusted operating expenses is a financial measure that has not been prepared in accordance with GAAP. Accordingly, investors should consider non-GAAP adjusted operating expenses in addition to, but not as a substitute for, operating expenses that we calculate and present in accordance with GAAP. Among other things, our management uses non-GAAP adjusted operating expenses to establish budgets and operational goals and to manage our business. Other companies may define or use this measure in different ways. We believe that the presentation of non-GAAP adjusted operating expenses provides investors and management with helpful supplemental information relating to operating performance and trends. A table reconciling non-GAAP adjusted operating expenses to operating expenses for all historical periods presented is included below under the heading "Reconciliation of Non-GAAP Adjusted Operating Expenses to Operating Expenses."

About Ovid Therapeutics

Ovid Therapeutics Inc. is a New York-based biopharmaceutical company striving to conquer seizures and brain disorders with courageous science. Ovid's pipeline of small molecule and genetic medicines candidates seek to meaningfully improve the lives of people and families affected by epilepsies. Ovid is developing OV329, a GABA aminotransferase inhibitor, for treatment-resistant seizures; and OV350, a direct activator of the KCC2 transporter, for potential treatment of epilepsies. In addition, Ovid maintains a significant financial interest in the future regulatory development and potential commercialization of soticlestat, which Takeda is

responsible for advancing globally. Soticlestat is a cholesterol 24 hydroxylase inhibitor, which is currently in Phase 3 trials for Dravet and Lennox-Gastaut syndromes. For more information about these and other Ovid research programs, 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 timing and development of Ovid's product candidate pipeline and achievement of expected near- and long-term milestones, including the filing of an IND for and anticipated timing of clinical trials of OV329, Ovid's business development intentions, the ability of Dr. Moss's team and lab to support the translation and development of Ovid candidates under the research agreement with Tufts University, the potential therapeutic benefits of Ovid's current or future product candidates, the continued development of soticlestat by Takeda, the clinical and regulatory development and potential commercialization of soticlestat, OV329, OV350, or any of Ovid's other current or future product candidates, and Ovid's expectations regarding its cash runway. You can identify forward-looking statements because they contain words such as "will," "believes," "intends," "anticipates" 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, without limitation, uncertainties inherent in the preclinical and clinical development and regulatory approval processes, risks related to Ovid's ability to achieve its financial objectives, the risk that Ovid may not be able to realize the intended benefits of its technology or its business strategy, risks related to Ovid's ability to identify business development targets or strategic partners, to enter into strategic transactions on favorable terms, or to consummate and realize the benefits of any business development transactions and risks to Ovid's or any of its partners' abilities to meet anticipated deadlines and milestones presented by the ongoing COVID-19 pandemic. Additional risks that could cause actual results to differ materially from those in the forward-looking statements are set forth under the caption "Risk Factors" in Ovid's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 15, 2022, and in future filings Ovid makes with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Ovid assumes no obligation to update any forward-looking statements contained herein, whether because of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

Condensed Consolidated Statements of Operations
Unaudited

	For The Three Months Ended March 31, 2022	For The Three Months Ended March 31, 2021
Revenue:		
License and other revenue	$ 1,445,366	$ 12,382,779
License revenue - related party	-	196,000,000
Total revenue	1,445,366	208,382,779
Operating expenses:		
Research and development	$ 7,832,269	$ 16,248,909
General and administrative	9,880,203	15,576,554
Total operating expenses	17,712,472	31,825,463
(Loss) income from operations	(16,267,107)	176,557,316
Other income (expenses), net	209,050	(49,732)
(Loss) income before provision for income taxes	(16,058,056)	176,507,584
Provision for income taxes	50,000	500,277
Net (loss) income	$ (16,108,056)	$ 176,007,307
Net (loss) income per share, basic	$ (0.23)	$ 2.55
Net (loss) income per share, diluted	$ (0.23)	$ 2.53
Weighted-average common shares outstanding, basic	70,345,828	66,088,592
Weighted-average common shares outstanding, diluted	70,345,828	66,578,377

Select Condensed Balance Sheet Data

Unaudited

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 166,668,027	$ 187,797,532
Working capital[1]	159,859,469	175,680,808
Total assets	191,096,074	194,544,757
Total stockholder's equity	164,996,271	179,746,436

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

Reconciliation of Non-GAAP Adjusted Operating Expenses to Operating Expenses

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Operating expenses	$ 17,712,472	$ 31,825,463
Non-recurring and non-cash items included therein:		
Stock-based compensation	1,324,812	1,320,002
Severance pay	1,978,286	-
Wind-down of OV101 clinical costs	243,187	3,750,280
Non-GAAP adjusted operating expenses	$ 14,166,188	$ 26,755,181

Contacts

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