

**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): November 10, 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.

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**Item 2.02. Results of Operations and Financial Condition.**

On November 10, 2021, Ovid Therapeutics Inc. (the “Company”) issued a press release providing a business update and corporate highlights and announcing third quarter 2021 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 into this Item 2.02.

**Item 7.01. Regulation FD Disclosure.**

On November 10, 2021, the Company posted its Corporate Overview dated November 2021 to the “News & Events” subsection of the “Investors” tab on the Company’s website at [www.ovidrx.com](http://www.ovidrx.com).

The information provided in Items 2.02 and 7.01, 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

<b>Exhibit No.</b>	<b><u>Description</u></b>
99.1	<a href="#">Press Release, dated November 10, 2021</a>
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

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Thomas M. Perone

General Counsel & Corporate Secretary

Dated: November 10, 2021



**Ovid Therapeutics Reports Third Quarter 2021 Business Update,  
Corporate Highlights and Financial Results**

- Ovid is implementing its business development program which intends to secure a series of opportunities that complement and enhance its pipeline of precision and small-molecule CNS medicines
- A development program for soticlestat, which Ovid licensed to Takeda, has begun enrolling patients in two pivotal, Phase 3 trials for Lennox-Gastaut and Dravet syndromes
- Company ended the third quarter of 2021 with cash and cash equivalents of \$201.8 million

**NEW YORK, November 10, 2021** — Ovid Therapeutics Inc. (NASDAQ: OVID), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological diseases, today provided a business update and reported corporate highlights and financial results for the quarter ended September 30, 2021.

Ovid reported its strategic intent to pursue a series of business development opportunities aimed at complementing and enhancing its pipeline of small-molecule and next-generation medicines. The Company seeks to acquire platform technologies for the purpose of delivering precision therapeutics that act on rare genetic targets in the brain. Additionally, Ovid plans to complement its early-stage pipeline with precision-medicine and small-molecule assets that align with its demonstrated clinical development competencies. The Company will prioritize potential medicines that can: deliver clear mechanistic targeting, leverage defined clinical endpoints, and fill significant needs for underserved rare disease communities.

“We have the capital, the expert team and the right strategy in place to unlock value in the rapidly growing field of rare neurology,” said Jeremy M. Levin, D.Phil, MB BChir, Chairman and Chief Executive Officer of Ovid Therapeutics. “With the perspectives of renowned biotech leaders who have recently joined our board and advisory team, we believe Ovid has the knowledge and access to pursue differentiated technologies and medicines for the brain. We look forward to providing updates on our business development activities.”

**Business Update**

- **Ovid conducted a strategic review of approximately 100 potential programs and confirmed desired areas of business development to apply its capital and expertise.** As part of this process, neuroscience and biotech experts from Ovid’s Board and Scientific and Clinical Advisory group have been actively involved in evaluating potential technologies and assets.

- **The Company will focus on acquiring and in-licensing assets for which it can shape the clinical development trajectory.** Ovid will seek to create best-in-class or first-in-class medicines that can have a meaningful impact on patients. Business development activities are focused on platform and delivery technologies, in addition to small molecule assets.
- **As part of its strategy, Ovid retained and strengthened its neuroscience talent so that it can rapidly integrate and execute on in-licensed or acquired programs.** The Company's team includes experts in clinical development, medical affairs, research and advocacy, who support Ovid's potential to be a partner-of-choice in rare neurology.
- **Ovid intends to submit three INDs in three years from its development programs.** The Company is targeting an IND submission for OV329, a next-generation GABA aminotransferase inhibitor that is being evaluated in tuberous sclerosis and infantile spasm seizures, in 2022.

#### Corporate Highlights

- **Two pivotal Phase 3 clinical trials evaluating soticlestat for Lennox Gastaut syndrome and Dravet syndrome are actively enrolling patients.** Ovid is eligible to receive regulatory and commercial milestones as well as tiered double-digit royalties, up to 20 percent on global sales of soticlestat, if it is approved and commercialized. Takeda is responsible for funding and operating both trials, and Ovid has no further financial obligations on soticlestat. If successful, Takeda estimates that it may receive regulatory approval of soticlestat in its fiscal year ending March 2024.
- **Kevin Fitzgerald, Ph.D., an accomplished leader in RNAi therapeutics development, joined the Board of Directors.** Dr. Fitzgerald brings to Ovid over 20 years of successful drug discovery experience and currently serves as the Chief Scientific Officer, Senior Vice President and Head of Research at Alnylam Pharmaceuticals, where he was instrumental in discovering and clinically validating two forms of siRNA delivery.

#### Third Quarter 2021 Financial Results

- Cash and cash equivalents as of September 30, 2021, were \$201.8 million.
- Revenue was zero for the quarter ended September 30, 2021, as compared to \$6.9 million for the same period in 2020. The revenue in the third quarter of 2020 was due to the recognition of a portion of an upfront payment received from Angelini Pharma.
- Research and development expenses were \$4.9 million for the quarter ended September 30, 2021, as compared to \$15.9 million for the same period in 2020. The decrease of \$11 million was primarily due to the wind-down of the clinical development of OV101 in Angelman syndrome and Fragile X syndrome and to the termination of Ovid's responsibilities to fund research and development expenses related to soticlestat's further development.

- General and administrative expenses were \$6.8 million for the quarter ended September 30, 2021, as compared to \$7.4 million the same period in 2020. The decrease of \$0.8 million was primarily a result of a decrease in ongoing payroll related expenses.
- Net loss was \$11.4 million for the quarter ended September 30, 2021, resulting in basic and diluted net loss per share of \$0.17. Net loss was \$16.4 million for the quarter ended September 30, 2020, resulting in basic and diluted net loss per share attributed to common stockholders of \$0.28.
- Operating expenses were \$11.7 million in the quarter ended September 30, 2021, and non-GAAP adjusted operating expenses (which exclude non-recurring expenses and non-cash expenses) were \$9.3 million for the third quarter. This expenditure was within the Company's non-GAAP adjusted guidance of \$8.0—\$10.0 million for the quarter. Ovid expects non-GAAP adjusted operating expenses to remain within the \$8.0—\$10.0 million range for the fourth quarter of 2021. 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, non-recurring and non-cash items: OV101 clinical costs, severance expense, and stock-based compensation, respectively. 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.” A quantitative reconciliation of projected non-GAAP adjusted operating expenses to operating expenses is not available without unreasonable effort primarily due to our inability to predict with reasonable certainty the amount of future stock-based compensation expense and non-recurring expenses.

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## 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 neurological disorders. Ovid seeks to couple deep CNS experience with emerging advances in genetics and the pathways of the brain to build a leading, next-generation neuroscience pipeline. Ovid's current 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 disorders; and other research targets. Additionally, Ovid maintains a significant financial interest in the future regulatory development and potential commercialization of soticlestat, which Takeda is responsible for advancing globally. Two Phase 3 trials for soticlestat in Dravet syndrome and Lennox-Gastaut syndrome are actively enrolling patients. For more information on Ovid, please visit [www.ovidrx.com](http://www.ovidrx.com).

## Forward-Looking Statements

This press release includes certain disclosures that contain “forward-looking statements,” including, without limitation, statements regarding the development and acceleration of Ovid's product candidate pipeline, Ovid's strategic approach and business development intentions and opportunities and ability to realize the desired benefits thereof, Ovid's ability to identify acquisition targets, the potential therapeutic benefits of Ovid's current or future product candidates, the clinical and regulatory development and potential commercialization of soticlestat, OV329 or any of Ovid's other current or future product candidates, Ovid's eligibility for potential milestone and royalty payments and Ovid's non-GAAP operating expense guidance for the fourth quarter of 2021. 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, 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, risks related to Ovid's ability to identify acquisition targets or strategic partners, to enter into strategic transactions on favorable terms, or to consummate and realize the benefits of any strategic transactions or acquisitions and risks to Ovid's or Takeda's 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 10, 2021, 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

	For The Three Months Ended September 30, 2021	For The Three Months Ended September 30, 2020	For The Nine Months Ended September 30, 2021	For The Nine Months Ended September 30, 2020
<b>Revenue:</b>				
License and other revenue	\$ —	\$ 6,914,034	\$ 12,382,779	\$ 6,914,034
License revenue - related party	—	—	196,000,000	—
<b>Total revenue</b>	<b>—</b>	<b>6,914,034</b>	<b>208,382,779</b>	<b>6,914,034</b>
<b>Operating expenses:</b>				
Research and development	\$ 4,917,393	\$ 15,875,295	\$ 28,849,969	\$ 46,533,610
General and administrative	6,764,341	7,442,401	28,970,053	20,220,160
<b>Total operating expenses</b>	<b>11,681,734</b>	<b>23,317,696</b>	<b>57,820,022</b>	<b>66,753,770</b>
<b>(Loss) income from operations</b>	<b>(11,681,734)</b>	<b>(16,403,662)</b>	<b>150,562,757</b>	<b>(59,839,736)</b>
Other income (expenses), net	2,657	(21,127)	(49,593)	833,661
<b>(Loss) income before (benefit) provision for income taxes</b>	<b>(11,679,077)</b>	<b>(16,424,789)</b>	<b>150,513,164</b>	<b>(59,006,075)</b>
<b>(Benefit) provision for income taxes</b>	<b>(294,829)</b>	<b>—</b>	<b>1,678,532</b>	<b>—</b>
<b>Net (loss) income</b>	<b>\$(11,384,248)</b>	<b>\$(16,424,789)</b>	<b>\$148,834,632</b>	<b>\$(59,006,075)</b>
Net (loss) income per share, basic	\$ (0.17)	\$ (0.28)	\$ 2.15	\$ (1.04)
Net (loss) income per share, diluted	\$ (0.17)	\$ (0.28)	\$ 2.14	\$ (1.04)
Weighted-average common shares outstanding, basic	67,929,894	59,406,215	67,282,495	56,586,640
Weighted-average common shares outstanding, diluted	67,929,894	59,406,215	67,848,033	56,586,640

### Select Condensed Balance Sheet Data

	(unaudited)	
	September 30, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	\$201,779,567	\$72,033,930
Working capital <sup>1</sup>	194,991,892	52,780,426
Total assets	207,086,188	75,925,518
Total stockholder's equity	197,021,761	43,631,656

<sup>1</sup>Working capital defined as current assets less current liabilities

## Reconciliation of Non-GAAP Adjusted Operating Expenses to Operating Expenses

	Quarter Ended September 30, 2021
Operating expenses	\$ 11,681,734
Non-recurring and non-cash items included therein:	
Stock-based compensation	1,161,911
Wind-down of OV101 clinical costs	1,105,283
Severance expense	106,746
Non-GAAP adjusted operating expenses	<u>\$ 9,307,794</u>

### Contacts

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