

**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): August 10, 2020

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 August 10, 2020, Ovid Therapeutics Inc. issued a press release announcing Second Quarter 2020 Financial Results and providing 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

Exhibit No.	Description
99.1	Press Release, dated August 10, 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: August 10, 2020



Ovid Therapeutics Reports Second Quarter 2020 Financial Results and Provides Corporate Update

- Announces completion of enrollment in the pivotal Phase 3 NEPTUNE trial with OV101 in Angelman syndrome; topline results expected in Q4 2020
- Multiple data readouts for soticlestat expected in Q3 2020, including from the randomized Phase 2 ELEKTRA trial in Dravet syndrome and Lennox-Gastaut syndrome, the Phase 2 ARCADE trial in CDKL5 deficiency disorder and Dup15q syndrome and the ENDYMION open-label extension study
- Receipt of Rare Pediatric Disease Designation by the FDA for OV101 for the treatment of Angelman syndrome, which if approved by the FDA can result in a priority review voucher
- Entered into an exclusive license agreement with Angelini Pharma to develop, manufacture and commercialize OV101 for the treatment of Angelman syndrome in Europe
- Expanded early-stage pipeline research activities through a license agreement with University of Connecticut School of Medicine and a strategic research collaboration with Columbia University Irving Medical Center

NEW YORK, August 10, 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 second quarter ended June 30, 2020 and provided a corporate update.

"Ovid is in an exciting and transformational period. We expect a number of important late-stage data readouts across our pipeline this quarter and over the remainder of the year," said Jeremy Levin, DPhil, MB, BChir, Chairman and Chief Executive Officer of Ovid Therapeutics. "We have completed enrollment in our pivotal Phase 3 NEPTUNE trial and expect topline results to be available in the fourth quarter. We also expect data from our comprehensive Phase 2 development program with soticlestat in four different rare developmental and epileptic encephalopathies during the third quarter. These upcoming data readouts, coupled with our recent commercial partnership with Angelini Pharma for OV101 in Europe, the receipt of Rare Pediatric Disease Designation from the FDA for OV101 in Angelman syndrome, and the expansion of our early-stage novel pipeline in genetics of rare neurological disease, have the potential to deliver near-term products and longer-term innovation, which will drive our

strategy. These important building blocks set the stage for Ovid to command a leading position in rare neurology."

Pipeline Updates and Recent Highlights

OV101 (gaboxadol) for Angelman Syndrome

- Ovid has completed enrollment in the pivotal Phase 3 NEPTUNE trial of OV101 in Angelman syndrome. Topline results from the trial are expected in the fourth quarter of 2020. NEPTUNE, if positive, will be part of a broad data set intended to support registrational filings for OV101 in the U.S. and the rest of the world.
- Ovid entered into an exclusive license agreement with Angelini Pharma to develop, manufacture and commercialize OV101 for the treatment of Angelman syndrome in Europe. Terms of the agreement include an upfront payment of \$20 million from Angelini with Ovid eligible to receive up to an additional \$212.5 million in payments upon the achievement of development, manufacturing and sales milestones for the initial indication (Angelman syndrome), as well as double-digit royalties, above the teens, on net sales if OV101 is successfully commercialized. Ovid retains all U.S. and rest-of-world commercial rights to OV101.
- In June 2020, the U.S. Food and Drug Administration (FDA) granted Rare Pediatric Disease Designation to OV101 for the treatment of Angelman syndrome. If a new drug application (NDA) for OV101 in Angelman syndrome is approved, Ovid may be eligible to receive a priority review voucher from the FDA, which can be redeemed to obtain priority review for any subsequent marketing application or may be transferred and/or sold to other companies.

OV101 for Fragile X Syndrome

- Ovid announced positive topline results from the Phase 2 ROCKET trial with OV101 in Fragile X syndrome in May 2020, and the Company plans to meet with regulatory authorities to discuss the future development path and registration pathway.

OV935 (soticlestat) for Rare Developmental and Epileptic Encephalopathies (DEE)

- Results from the Phase 2 ARCADE trial in CDKL5 deficiency disorder (CDD) and Dup15q syndrome are expected in the third quarter of 2020.
- Results from the randomized Phase 2 ELEKTRA trial in patients with Dravet syndrome and Lennox-Gastaut syndrome (LGS) are expected in the third quarter of 2020.
- To date, all patients who have completed the Phase 2 ARCADE and ELEKTRA trials have rolled over into the ENDYMION open-label extension study. Ovid plans to report updated data from ENDYMION in the third quarter of 2020.

Summary of Anticipated Clinical Data Readouts

Product Candidate	Trial	Condition or Disease	Phase of Clinical Trial	Expected Timing of Release
Soticlestat	ARCADE	CDD or Dup15q syndrome	Phase 2	3Q 2020
Soticlestat	ELEKTRA	Dravet syndrome or LGS	Phase 2	3Q 2020
Soticlestat	ENDYMION	CDD, Dup15q syndrome, Dravet syndrome, LGS, other DEEs	Open-label Extension	3Q 2020
OV101	NEPTUNE	Angelman syndrome	Phase 3	4Q 2020

Expansion of Early-Stage Pipeline Research Activities

- Ovid and the University of Connecticut School of Medicine (UConn) announced a license agreement to accelerate the development of a next-generation short hairpin RNA (shRNA)-based therapeutic for Angelman syndrome and potentially other indications. Ovid will work closely with UConn's Stormy J. Chamberlain, Ph.D., and gain exclusive access to identified genetic sequences for a shRNA-based therapeutic for potential future use alone or in combination with OV101 in Angelman syndrome.
- Ovid entered into a research collaboration with Columbia University Irving Medical Center researchers to focus on development of potential medicines using genetic-based therapies and create a therapeutic platform for a range of rare neurological conditions such as KIF1A-associated neurological disorder (KAND).

Pipeline Teach-In Webinar Series

- In June 2020, Ovid hosted a webinar to review the Company's soticlestat development program for rare developmental and epileptic encephalopathies (DEE).
- Ovid is planning to hold a second educational webinar early in the fourth quarter of 2020 to review the Company's OV101 development program for Angelman syndrome and Fragile X syndrome.

Second Quarter 2020 Financial Results

- As of June 30, 2020, cash and cash equivalents totaled \$41.3 million. Additionally, the Company received an upfront net payment from Angelini Pharma of \$19.6 million in July 2020.
- Research and development expenses were \$16.0 million for the second quarter ended June 30, 2020, as compared to \$9.1 million for the same period in 2019. The increase of \$6.9 million was

primarily due to an increase in clinical activities related to Ovid's ongoing development programs.

- General and administrative expenses were \$7.1 million for the second quarter ended June 30, 2020, as compared to \$4.2 million for the same period in 2019. The increase of \$2.9 million was primarily due to an increase in legal fees, compliance and pre-commercialization expenses and professional fees, payroll and payroll-related expenses and general office expenses.
- The Company reported a net loss of \$22.6 million, or basic and diluted net loss per share attributable to common stockholders of \$0.41, for the second quarter of 2020, as compared to a net loss of \$13.1 million, or net loss per share attributable to common stockholders of \$0.34, for the same period in 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. 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 www.ovidrx.com.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding: development and commercialization of our programs, development of combination therapies, potential benefits of OV101, OV935 and our other research programs, anticipated reporting schedule of clinical data and the potential benefits and value of certain licenses and collaborations and the potential benefits of the Rare Pediatric Disease Designation. 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, 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". 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 June 30, 2020	For the Three Months Ended June 30, 2019	For the Six Months Ended June 30, 2020	For the Six Months Ended June 30, 2019
Operating expenses:				
Research and development	\$ 16,032,945	\$ 9,117,495	\$ 30,658,313	\$ 18,454,804
General and administrative	7,108,742	4,204,771	12,777,759	8,920,999
Total operating expenses	23,141,687	13,322,266	43,436,072	27,375,803
Loss from operations	(23,141,687)	(13,322,266)	(43,436,072)	(27,375,803)
Interest income	590,491	264,999	854,786	518,341
Net loss	\$ (22,551,196)	\$ (13,057,267)	\$ (42,581,286)	\$ (26,857,462)
Net loss attributable to common stockholders	\$ (22,551,196)	\$ (13,057,267)	\$ (42,581,286)	\$ (26,857,462)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.41)	\$ (0.34)	\$ (0.77)	\$ (0.78)
Weighted-average common shares outstanding basic and diluted	55,607,110	38,693,018	55,161,360	34,534,432

Selected Condensed Balance Sheet Data
(Unaudited)

	June 30, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	\$ 41,253,898	\$ 76,739,113
Working capital ¹	\$ 29,524,782	\$ 69,279,584
Total assets	\$ 45,355,298	\$ 80,843,731
Total stockholders' equity	\$ 30,482,914	\$ 70,023,561

¹Working capital defined as current assets less current liabilities

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