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

November 12, 2020

- On track to report topline results from pivotal Phase 3 NEPTUNE trial of OV101 in Angelman syndrome in Q4 2020
- Reported positive ELEKTRA results; Ovid and Takeda plan to initiate phase 3 registrational program of OV935/TAK935 (soticlestat) in Dravet Syndrome and Lennox-Gastaut syndrome after upcoming end-of-phase 2 meeting with FDA
- Reported encouraging trial results from ARCADE open-label Phase 2 trial of soticlestat and ENDYMION long-term extension trial showing seizure frequency reductions over time in CDKL5 deficiency disorder and Dup15q syndrome and global improvements beyond motor seizure reduction in both CDKL5 deficiency disorder and Dup15q syndrome patients
- In the ELEKTRA, ARCADE and ENDYMION trials, soticlestat appeared to be well-tolerated and demonstrated a safety profile consistent with the findings of previous studies with no new safety signals identified

NEW YORK, Nov. 12, 2020 (GLOBE NEWSWIRE) -- 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 third quarter ended September 30, 2020 and provided a corporate update.

"We are very pleased with the progress made on our pipeline this quarter, which was highlighted by encouraging results from both the ELEKTRA and the ARCADE Phase 2 trials of OV935," said Jeremy Levin, DPhil, MB, BChir, Chairman and Chief Executive Officer of Ovid Therapeutics. "We look forward to advancing OV935 into a Phase 3 program for Dravet syndrome and Lennox-Gastaut syndrome next year after our end-of-phase 2 meeting with FDA. We are continuing to explore further clinical development opportunities in CDKL5 deficiency disorder, and Dup15q syndrome. Additionally, we remain on track to report topline data for the pivotal Phase 3 NEPTUNE trial of OV101 in Angelman syndrome this quarter. Pending a successful NEPTUNE readout, OV101 has the potential to become the first-ever treatment approved for Angelman syndrome, a disorder affecting some 500,000 patients worldwide."

Pipeline Updates and Recent Highlights

OV101 (gaboxadol) for Angelman Syndrome

- Hosted an investor seminar to review multiple aspects of Angelman syndrome, including its biological mechanism, and Ovid's OV101 (gaboxadol) development program. The seminar featured external experts discussing the role of tonic inhibition, treatment practice in Angelman syndrome, measurement scales, and what to expect from the pivotal Phase 3 NEPTUNE trial of OV101 in Angelman syndrome. Topline results from NEPTUNE are expected in the fourth quarter of 2020. Results, if positive, are intended to support registrational filings for OV101 in the U.S. and the rest of the world.

- Presented three abstracts from the OV101 Angelman syndrome clinical development program at the Child Neurology Society/International Child Neurology Association (CNS/ICNA) 2020 Virtual Congress. The presentations included data on seizure and EEG outcomes from the Phase 2 STARS trial in individuals with Angelman syndrome; encore presentations of a study of caregiver insights in Angelman syndrome; and the utility of the Clinical Global Impression (CGI) scale for studying outcomes in neurodevelopmental conditions.

OV101 for Fragile X Syndrome

- Presented an abstract from the OV101 Fragile X syndrome clinical development program at the Child Neurology Society/International Child Neurology Association (CNS/ICNA) 2020 Virtual Congress. The presentation included additional data and analyses from the Phase 2 ROCKET clinical trial of OV101 in individuals with Fragile X syndrome.

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

- Announced that the double-blind, randomized placebo-controlled, Phase 2 ELEKTRA trial of soticlestat met its primary endpoint in children with Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS).

° Results showed a 27.8% median reduction from baseline in convulsive seizure (DS cohort) and drop seizure (LGS cohort) frequency compared to a 3.1% median increase in patients taking placebo during the 12-week maintenance period (median placebo-adjusted reduction=30.5%; p=0.0007, based on the efficacy analysis set of 120 patients with seizure data in the maintenance period).

° DS and LGS patients treated with soticlestat demonstrated a 29.8% median reduction in convulsive seizure (DS cohort) and drop seizure (LGS cohort) frequency compared to 0.0% change in median seizure frequency in patients taking placebo during the full 20-week treatment period (titration plus maintenance) of the ELEKTRA study (placebo-adjusted reduction=25.1%; p=0.0024).

° In the ELEKTRA DS cohort (n=51), patients treated with soticlestat demonstrated a 33.8% median reduction in convulsive seizure frequency

compared to a 7.0% median increase in patients taking placebo during the full 20-week treatment period of the study (median placebo-adjusted reduction in seizure frequency is 46.0%; p=0.0007).

° In the ELEKTRA LGS cohort (n=88), patients treated with soticlestat demonstrated a 20.6% median reduction in drop seizure frequency compared to a 6.0.% median reduction in patients taking placebo during the full 20-week treatment period of the study (median placebo-adjusted reduction in seizure frequency is 14.8%; p=0.1279).

- Ovid and Takeda plan to meet with regulatory authorities regarding initiating a Phase 3 registrational program of soticlestat in individuals with DS or LGS.

- Reported results from the Phase 2 ARCADE and ENDYMION OLE trials of OV935 in patients with CDKL5 deficiency disorder (CDD) and Dup15q syndrome showing seizure frequency reduction over time.

° In CDD patients (n=12), median motor seizure frequency reduction was 24% during the 12-week maintenance period in the ARCADE study, increasing to a 50% reduction in the 9-month interval in the ENDYMION long-term extension study in the five CDD patients who reached nine months of continuous treatment.

° In Dup15q patients (n=8), there was an increase in median motor seizure frequency in the ARCADE study during the 12-week maintenance period; however, longer-term data from the four Dup15q patients who reached nine months of continuous treatment showed a 74% reduction in median motor seizure frequency in the 9-month interval.

° Global Improvements were reported in both patient populations as assessed by the Clinical Global Impression of Change (CGI-C; investigator) and Caregiver Global Impression of Change (Care GI-C) scales. 67% of CDD patients and 38% of Dup15q were deemed markedly improved with minimal or no adverse events on the CGI-C scale after starting soticlestat treatment. For the Care-GI-C scale, 92% of CDD caregivers reported improvement on soticlestat treatment at the end of the ARCADE study, with 41% reporting much and very much improved.

° The ARCADE study exit interviews from the caregiver also give insight into improvements in verbal and nonverbal communication, alertness/level of engagement, overall quality of daily functioning and caregiver-chosen domains to suggest benefits of soticlestat treatment in domains beyond seizure control.

- OV935 was generally well tolerated in the ELEKTRA, ARCADE and ENDYMION studies and demonstrated a safety profile consistent with the findings of previous studies with no new safety signals identified. Data reported are consistent with, and build upon, previous findings with OV935.

- To date, all patients who have completed the Phase 2 ARCADE and ELEKTRA trials have rolled over into the ENDYMION open-label extension study.

Third Quarter 2020 Financial Results

- Revenue was $6.9 million for the third quarter ended September 30, 2020, as compared to zero for the same period in 2019. The increase was due to the receipt of the $20 million upfront payment under the collaboration and license agreement with Angelini Pharma Rare Diseases AG, of which $6.9 million was recognized in the third quarter as revenue and $13.1 million was deferred.

- As of September 30, 2020, cash and cash equivalents totaled $86.9 million. The Company strengthened its financial position with the completion of a public offering in August 2020, resulting in net proceeds of approximately $46.7 million.

- Research and development expenses were $15.9 million for the third quarter ended September 30, 2020, as compared to $11.6 million for the same period in 2019. The increase of $4.3 million was primarily due to an increase in preclinical and clinical activities related to Ovid's ongoing development programs.

- General and administrative expenses were $7.4 million for the third quarter ended September 30, 2020, as compared to $5.2 million for the same period in 2019. The increase of $2.2 million was primarily due to an increase in professional service fees, compliance and pre-commercialization expenses, payroll and payroll-related expenses offset by a decrease in general office expenses.

- The Company reported a net loss of $16.4 million, or basic and diluted net loss per share attributable to common stockholders of $0.28, for the third quarter of 2020, as compared to a net loss of $16.6 million, or net loss per share attributable to common stockholders of $0.43, 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 in development. 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 (DEEs). 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: clinical and regulatory development of our programs, potential benefits of OV101, OV935 and our other research programs and the anticipated reporting schedule of clinical data and the potential benefits. 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 September 30, 2020	For the Three Months Ended September 30, 2019	For the Nine Months Ended September 30, 2020	For the Nine Months Ended September 30, 2019
Revenue:				
License revenue	$ 6,914,034	$ -	$ 6,914,034	$ -
Operating expenses:				
Research and development	$ 15,875,295	$ 11,597,633	$ 46,533,610	$ 30,052,432
General and administrative	7,442,401	5,168,103	20,220,160	14,089,106
Total operating expenses	23,317,696	16,765,736	66,753,770	44,141,538
Loss from operations	(16,403,662)	(16,765,736)	(59,839,736)	(44,141,538)
Other (expense) income, net	(21,127)	131,164	833,661	649,504
Net loss	$ (16,424,789)	$ (16,634,572)	$ (59,006,075)	$ (43,492,034)
Net loss attributable to common stockholders	$ (16,424,789)	$ (16,634,572)	$ (59,006,075)	$ (43,492,034)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (0.43)	$ (1.04)	$ (1.21)
Weighted-average common shares outstanding basic and diluted	59,406,215	38,504,825	56,586,640	35,872,441

Selected Condensed Balance Sheet Data
(Unaudited)

	September 30, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 86,866,275	$ 76,739,113
Working capital[1]	72,387,568	69,279,584
Total Assets	91,599,016	80,843,731
Total stockholder's equity	63,643,038	70,023,561

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

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