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Ovid Therapeutics Reports Second Quarter 2017 Financial Results and Corporate Progress

NEW YORK, Aug. 10, 2017 (GLOBE NEWSWIRE) -- Ovid Therapeutics Inc. (NASDAQ:OVID), a biopharmaceutical company committed to developing medicines for patients with rare neurological disorders, today announced financial results for the second quarter ended June 30, 2017 and provided an overview of the company's recent business progress.

"Ovid continues to build a robust pipeline of promising medicines. We have made important progress over the last quarter in all our programs," said Jeremy Levin, DPhil, MB BChir, chairman and chief executive officer of Ovid Therapeutics. "In collaboration with Takeda, we have rapidly advanced TAK935/OV935 into a Phase 1b/2a clinical trial in rare epilepsies. We have set the stage for a broader development strategy, including a pediatric program and biomarker strategy. The initiation of this trial, along with the two clinical trials for OV101 in neurodevelopmental disorders we commenced earlier this year, demonstrates our execution and underscores our commitment to deliver impactful medicines for those living with devastating rare neurological disorders."

Recent Highlights and Upcoming Milestones

OV101 for Neurodevelopmental Disorders

- Ovid continues to enroll patients in the Phase 2 STARS clinical trial of OV101 in adults with Angelman syndrome. The company expects topline data from the STARS trial to be available in 2018.

- The company also continues to enroll patients in a Phase 1 clinical trial to evaluate the safety, pharmacokinetics (PK) and tolerability of OV101 in adolescents diagnosed with Angelman syndrome or Fragile X syndrome aged 13 to 17 years. The company expects

topline data to be available in the second half of 2017.

- Ovid also is planning to initiate clinical development in a younger pediatric population pending completion of the adolescent PK trial and juvenile animal toxicity studies.

OV935 for Epileptic Encephalopathies

- Ovid and Takeda initiated a Phase 1b/2a clinical trial with OV935 to treat rare developmental and/or epileptic encephalopathies. The primary endpoint of the study is to characterize the safety and tolerability of OV935. Secondary endpoints include assessment of standard safety laboratory values and evaluation of pharmacokinetics (PK).

Corporate

- Strengthened the company's board of directors with the appointment of Barbara G. Duncan, who will serve as chairperson of the Audit Committee.

- Completed an initial public offering (IPO) of 5,000,000 shares of common stock, raising gross proceeds of $75 million, prior to deducting the underwriting discount and estimated expenses of the offering.

Second Quarter 2017 Financial Results

- As of June 30, 2017, cash and cash equivalents totaled $106.1 million.

- Research and development expenses were $6.1 million for the second quarter of 2017, as compared to $1.8 million for the same period in 2016. The increase was primarily due to higher clinical expenses related to the clinical studies of OV101, costs related to the Takeda collaboration for OV935, preclinical development expenses, and an increase in payroll and payroll-related expenses due to increased headcount as the company expanded its operations.

- General and administrative expenses were $4.2 million for second quarter of 2017, as compared to $3.6 million for the same period in 2016. The increase was primarily due to the increase in payroll and payroll-related expenses due to increased headcount as the company expanded its operations.

- The company reported net losses of $10.2 million, or basic and diluted net loss per share attributable to common stockholders of $0.57, for the second quarter of 2017, as compared to a loss of $5.4 million, or basic and diluted net loss per share attributable to common stockholders of $0.55, for the same period in 2016.

About OV101
OV101 (gaboxadol) is believed to be the only delta (δ)-selective $GABA_A$ receptor agonist in development and the first investigational drug to specifically target the disruption of tonic inhibition that is thought to be the underlying cause of certain neurodevelopmental disorders. OV101 has been demonstrated in laboratory studies and animal models to selectively activate the δ-subunit of $GABA_A$ receptors, which are found in the extrasynaptic space (outside of the synapse), and thereby impact neuronal activity through tonic inhibition.

Ovid is developing OV101 for the treatment of Angelman syndrome and Fragile X syndrome to potentially restore tonic inhibition and relieve several of the symptoms of these disorders. In preclinical studies, it was observed that OV101 improved symptoms of Angelman syndrome and Fragile X syndrome.

In September 2016, the FDA granted orphan drug designation for OV101 for the treatment of Angelman syndrome. The United States Patent and Trademark Office has granted Ovid two patents directed to methods of treating Angelman syndrome using OV101. The issued patents expire in 2035, without regulatory extensions.

About OV935
OV935, which is being studied in rare epilepsies, is a potent, highly-selective, first-in-class inhibitor of the enzyme cholesterol 24-hydroxylase (CH24H). CH24H is predominantly expressed in the brain, where it plays a central role in cholesterol homeostasis. CH24H converts cholesterol to 24-S-hydroxycholesterol (24HC) which then exits the brain into the blood plasma circulation. Glutamate is one of the main neurotransmitters in the brain and has been shown to play a role in the initiation and spread of seizure activity. Recent literature indicates CH24H is involved in over-activation of the glutamatergic pathway through modulation of the NMDA channel, implying its potential role in central nervous system diseases such as epilepsy. To Ovid's knowledge, OV935 is the only molecule with this mechanism of action in clinical development.

OV935 has been tested in preclinical models to provide data to support the advancement of the drug into human clinical studies in patients suffering from rare epilepsy syndromes. A novel proprietary PET ligand, developed by Takeda and Molecular Neuroimaging, LLC (MNI), has been used to determine

target occupancy of OV935 in the brain. In addition, OV935's effect on CH24H enzyme activity in the brain has been assessed by following measurable reductions in the plasma concentration of 24HC.

OV935 has completed four Phase 1 clinical studies which have assessed tolerability and target engagement at doses which are believed to be therapeutically relevant. OV935 is being co-developed by Ovid and Takeda Pharmaceutical Company Limited.

About Ovid Therapeutics
Ovid Therapeutics (NASDAQ:OVID) is a New York-based, biopharmaceutical company using its BoldMedicine™ approach to develop therapies that transform the lives of patients with rare neurological disorders. Ovid's drug candidate, OV101, is currently in development for the treatment of Angelman syndrome and Fragile X syndrome. Ovid has initiated the Phase 2 STARS trial of OV101 in adults with Angelman syndrome and a Phase 1 trial in adolescents with Angelman syndrome or Fragile X syndrome. Ovid is also developing OV935 in collaboration with Takeda Pharmaceutical Company Limited for the treatment of rare epileptic encephalopathies and has initiated a Phase 1b/2a trial of OV935.

For more information on Ovid, please visit http://www.ovidrx.com/ (https://www.globenewswire.com/Tracker?data=yJeS6Eb0c-RR0U3VIuQfrPI-XVmgf22YtnDbTICW1M268GMYKitRiwoIaWM5DIX2cFgGh6DYM8Xt_tCigQILSc3byARHBojrNLOjKJ_unicOqgOakqdOOoTHj_02xXOoNtdS5LD57P1oDwQQUVEd6gwmc8kUpbAzXn4ObL2CutQXb9E4sNycntXPlyPm11kMzcVqU9FgKwyADKU645rden1TfXlEBsYxnoA7PgtHF6XIPbcxsI11ljSKzZgPnS_BqyEUefrvkfGsIIhqRnMDIQ==).

Forward-Looking Statements
This press release includes certain disclosures which contain "forward-looking statements," including, without limitation, statements regarding progress, timing, scope and results of clinical trials for Ovid's product candidates and the reporting of clinical data regarding Ovid's product candidates. You can identify forward-looking statements because they contain words such as "will," "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 are set forth in Ovid's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, under the caption "Risk Factors." Ovid assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

OVID THERAPEUTICS INC.
Condensed Balance Sheets

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 106,115,648	$ 51,939,661
Prepaid and other current assets	1,195,669	221,507
Due from related parties	-	7,369
Deferred transaction costs	-	242,673
Total current assets	107,311,317	52,411,210
Security deposit	430,275	407,785
Property, plant and equipment, net	49,798	43,591
Other assets	215,748	165,301
Total assets	$ 108,007,138	$ 53,027,887
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,571,534	$ 857,169
Accrued expenses	3,493,493	2,876,243
Total current liabilities	7,065,027	3,733,412
Stockholders' Equity:		
Common stock, $0.001 par value; 125,000,000 and 58,000,000 shares authorized at June 30, 2017 and December 31, 2016, respectively, 24,601,936 and 9,838,590 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	24,602	9,839
Preferred Series A - zero and 5,121,453 shares authorized at June 30, 2017 and December 31, 2016, respectively zero and 2,382,069 issued and outstanding at June 30, 2017 and December 31, 2016, respectively	-	2,382
Preferred Series B - zero and 12,038,506 shares authorized at June 30, 2017 and December 31, 2016, respectively zero and 5,599,282 issued and outstanding at June 30, 2017 and December 31, 2016, respectively	-	5,599
Additional paid-in-capital	181,314,312	85,186,269
Accumulated deficit	(80,396,803)	(35,909,614)
Total stockholders' equity	100,942,111	49,294,475
Total liabilities and stockholders' equity	$ 108,007,138	$ 53,027,887

OVID THERAPEUTICS INC.
Condensed Statements of Operations and Comprehensive Loss

	For the Three Months Ended June 30, 2017	For the Three Months Ended June 30, 2016	For the Six Months Ended June 30, 2017	For the Six Months Ended June 30, 2016
Operating expenses:				
Research and development	$ 6,074,927	$ 1,770,202	$ 37,359,355	$ 2,896,804
General and administrative	4,213,173	3,646,731	7,191,039	6,234,624
Total operating expenses	10,288,100	5,416,933	44,550,394	9,131,428
Loss from operations	(10,288,100)	(5,416,933)	(44,550,394)	(9,131,428)
Interest income	39,721	31,307	63,205	63,636
Net loss and comprehensive loss	$ (10,248,379)	$ (5,385,626)	$ (44,487,189)	$ (9,067,792)
Net loss attributable to common stockholders	$ (10,248,379)	$ (5,385,626)	$ (44,487,189)	$ (9,067,792)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (0.55)	$ (3.18)	$ (0.92)
Weighted-average common shares outstanding basic and diluted	18,112,554	9,838,590	13,998,428	9,838,590

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