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Ovid Therapeutics Reports First Quarter 2017 Financial Results and Recent Corporate Progress

Completed Initial Public Offering Raising $75 Million in Gross Proceeds

Initiated Phase 2 STARS Clinical Trial of OV101 in Adults with Angelman Syndrome

Entered into Innovative Global Collaboration with Takeda Focused on the Clinical Development and Commercialization of TAK-935/OV935 in Rare Pediatric Epilepsies

NEW YORK, June 13, 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 first quarter ended March 31, 2017 and provided an overview of the company's recent progress.

"Ovid has a clear strategy and business plan to build a neurology company focused on rare disorders of the brain. Earlier this year we initiated two clinical trials for OV101, a Phase 2 ("STARS") trial in adults with Angelman syndrome and a Phase 1 trial in adolescents with either Angelman syndrome or Fragile X syndrome," said Jeremy Levin, DPhil, MB BChir, chairman and chief executive officer of Ovid Therapeutics. "In addition, we entered into a collaboration with Takeda Pharmaceutical Company Limited to develop and commercialize TAK-935/OV935 for rare epileptic encephalopathies. Building on the momentum in the company we successfully closed our initial public offering in May. We look forward to continued progress throughout 2017 and beyond."

Recent Highlights and Upcoming Milestones

- Successfully completed the company's initial public offering (IPO), raising $75.0 million in gross proceeds.

- Initiated the Phase 2 STARS clinical trial of OV101 in adults with Angelman syndrome, a rare genetic disorder with no FDA-approved therapies.
    - The trial is expected to enroll approximately 75 adults aged 18 to 49 years in the United States and Israel with a confirmed diagnosis of Angelman syndrome.
    - The primary endpoint of the trial is to assess the safety and tolerability of OV101. Exploratory endpoints include evaluating measures of gross and fine motor skills, maladaptive behavior, sleep, clinical global impression and health-related quality of life questionnaires.
    - The company expects topline data from the STARS trial to be available in 2018.

- Initiated a Phase 1 clinical trial to evaluate OV101 in adolescents diagnosed with Angelman syndrome or Fragile X syndrome aged 13 to 17 years.
    - The Phase 1 single dose, single-arm, open-label clinical trial will measure pharmacokinetics (PK), safety and tolerability of OV101.
    - 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 a pediatric PK trial and juvenile animal toxicity studies.

- Launched a biomarker strategy to identify molecular markers of treatment responders in neurodevelopmental disorders.
  - Ovid entered into a services agreement with NeuroPointDX. The relationship will focus on identifying novel biomarkers of Angelman syndrome by analyzing metabolomic profile data generated in the STARS trial.

- Expanded the pipeline by entering into a global collaboration with Takeda Pharmaceutical Company Limited focused on the clinical development and commercialization of TAK-935/OV935, a potent and highly selective CH24H inhibitor, in rare epileptic encephalopathies.
  - The companies share in the development and commercialization costs on a 50/50 basis and, if successful, the companies will share in the profits on a 50/50 basis.
  - Ovid will lead clinical development activities and commercialization of OV935 in the United States, Europe, Canada and Israel.
  - The companies plan to initiate a Phase 1b/2a trial in 2017 in patients with rare epileptic encephalopathies, including Dravet syndrome, Lennox-Gastaut syndrome and Tuberous Sclerosis Complex.

- Presented preclinical data for OV935 at an oral presentation at the Antiepileptic Drug and Device (AEDD) Trials XIV Conference in May 2017.

- Strengthened the company's Scientific Advisory Board with the appointment of Jacqueline A. French, M.D., a world-renowned expert in the treatment of epilepsy.

First Quarter 2017 Financial Results

- As of March 31, 2017, cash and cash equivalents totaled $44.2 million. On May 10, 2017, the company completed its IPO of 5,000,000 shares of common stock at a public offering price of $15.00 per share, raising gross proceeds of $75 million, prior to deducting the underwriting discount and estimated expenses of the offering.

- Research and development expenses were $31.3 million for the first quarter of 2017, as compared to $1.1 million for the same period in 2016. The increase was primarily due to the issuance of stock to Takeda as an upfront payment upon signing the collaboration agreement for OV935. Of the $27.5 million in collaboration agreement expenses, $25.9 million related to the issuance of common stock to Takeda and $1.6 million in Takeda alliance costs. Additional higher expenses relating to the STARS Phase 2 trial for OV101 accounted for the rest of the increase in 2017.

- General and administrative expenses were $3.0 million for first quarter of 2017, as compared to $2.6 million for the same period in 2016. The increase was primarily due to the increase in payroll and payroll-related expenses as a result of increased headcount as we expand our operations.

The Company reported net losses of $34.2 million, or basic and diluted net loss per share attributable to common stockholders of $3.48, for the first quarter of 2017, as compared to a loss of $3.7 million, or basic and diluted net loss per share attributable to common stockholders of $0.37, 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 THIP (OV101). The issued patents expire in 2035, without regulatory extensions.

About TAK-935
TAK-935, which is being studied in rare pediatric 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.[i] 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.[ii] Recent literature indicates CH24H is involved in over-activation of the glutamatergic pathway through modulation of the NMDA channel,[iii] implying its potential role in CNS diseases such as epilepsy. To Ovid's knowledge, TAK-935 is the only molecule with this mechanism of action in clinical development.

TAK-935 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 TAK-935 in the brain.[iv] In addition, TAK-935's effect on CH24H enzyme activity in the brain has been assessed by following measurable reductions in the plasma concentration of 24HC.

TAK-935 has completed four Phase 1 clinical studies[v],[vi],[vii],[viii] which have assessed tolerability and target engagement at doses which are believed to be therapeutically relevant. TAK-935 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. Ovid expects to initiate a Phase 1b/2a trial of OV935 to treat rare epileptic encephalopathies in 2017.

For more information on Ovid, please visit http://www.ovidrx.com/.

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, the reporting of clinical data regarding Ovid's product candidates, and the potential use of TAK-935/OV935 to treat epileptic encephalopathies. 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 registration statement on Form S-1, as amended, 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 (unaudited)

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 44,225,807	$ 51,939,661
Prepaid and other current assets	389,360	221,507
Due from related parties	-	7,369
Deferred transaction costs	1,926,017	242,673
Total current assets	46,541,184	52,411,210
Security deposit	415,260	407,785
Property, plant and equipment, net	46,586	43,591
Other assets	200,281	165,301
Total assets	$ 47,203,311	$ 53,027,887
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,579,789	$ 857,169
Accrued expenses	3,287,974	2,876,243
Total current liabilities	4,867,763	3,733,412
Stockholders' Equity:		
Common stock, $0.001 par value; 62,000,000 and 58,000,000 shares authorized at March 31, 2017 and December 31, 2016, respectively, 9,838,590 shares issued and outstanding at March 31, 2017 and December 31, 2016	9,839	9,839
Preferred Series A - 5,121,453 shares authorized at March 31, 2017 and December 31, 2016, 2,382,069 issued and outstanding at March 31, 2017 and December 31, 2016 (liquidation preference $5,060,000)	2,382	2,382
Preferred Series B - 12,038,506 shares authorized, 5,599,282 issued and outstanding at March 31, 2017 and December 31, 2016 (liquidation preference $74,999,883)	5,599	5,599
Preferred Series B-1 - 3,831,923 and zero shares authorized at March 31, 2017 and December 31, 2016, respectively, 1,781,996 and zero issued and outstanding at March 31, 2017 and December 31, 2016, respectively	1,782	-
Additional paid-in-capital	112,464,370	85,186,269
Accumulated deficit	(70,148,424)	(35,909,614)
Total stockholders' equity	42,335,548	49,294,475
Total liabilities and stockholders' equity	$ 47,203,311	$ 53,027,887

OVID THERAPEUTICS INC.
Condensed Statements of Operations and Comprehensive Loss (unaudited)

	Three Months Ended March 31,	Three Months Ended March 31,

	2017	2016
Operating expenses:		
Research and development	$ 31,284,429	$ 1,126,602
Selling, general and administrative	2,977,864	2,587,894
Total operating expenses	34,262,293	3,714,496
Interest income (expense), net	23,483	32,330
Loss before income tax	(34,238,810)	(3,682,166)
Income taxes	-	-
Net loss and comprehensive loss	$ (34,238,810)	$ (3,682,166)
Net loss attributable to common stockholders	$ (34,238,810)	$ (3,682,166)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.48)	$ (0.37)
Weighted-average common shares outstanding basic and diluted	9,838,590	9,838,590

[i] Russell DW, Halford RW, Ramirez DMO, Shah R, Kotti T. Cholesterol 24-Hydroxylase: An Enzyme of Cholesterol Turnover in the Brain. Annu Rev Biochem. 2009; 78: 1017–1040.

[ii] Mehta A, Prabhakar M, Kumar P, Deshmukh R, Sharma PL. Excitotoxicity: bridge to various triggers in neurodegenerative disorders. Eur J Pharmacol 2013;698(1-3):6-18.

[iii] Paul SM, Doherty JJ, Robichaud AJ, Belfort GM, Chow BY, Hammond RS, et al. The major brain cholesterol metabolite 24(S)-hydroxycholesterol is a potent allosteric modulator of N-methyl-D-aspartate receptors. J Neurosci 2013;33(44):17290-300.

[iv] https://www.clinicaltrials.gov/ct2/show/NCT02497235?term=TAK-935&rank=1

[v] https://www.clinicaltrials.gov/ct2/show/NCT02497235?term=TAK-935&rank=1

[vi] https://www.clinicaltrials.gov/ct2/show/NCT02906813?term=TAK-935&rank=2

[vii] https://www.clinicaltrials.gov/ct2/show/NCT02201056?term=TAK-935&rank=3

[viii] https://www.clinicaltrials.gov/ct2/show/NCT02539134?term=TAK-935&rank=4

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