OVID THERAPEUTICS INC.

FORM 8-K
(Current report filing)

Filed 06/09/17 for the Period Ending 06/09/17

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SIC Code 2834 - Pharmaceutical Preparations
Industry Biotechnology & Medical Research
Sector Healthcare
Fiscal Year 12/31
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):
June 9, 2017

Ovid Therapeutics Inc.
(Exact name of registrant as specified in its charter)

Delaware 001-38085 46-5270895
(Exact Name of Registrant As Specified In Its Charter) (Commission File Number) (I.R.S. Employer Identification No.)

1460 Broadway, Suite 15044
New York, New York 10036
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (646) 661-7661

Check if the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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. ☒

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 Instruction 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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On June 9, 2017, Ovid Therapeutics Inc. (the “Company”) posted its corporate presentation, dated June 9, 2017, to the “Events & Presentations” subsection of the “Investors & Media” tab on the Company’s website at www.ovidrx.com. A copy of the corporate presentation is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01.

This information, including the Exhibit 99.1 referenced herein, is “furnished” and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended, only if and to the extent such subsequent filing specifically references the information herein as being incorporated by reference in such filing.

Cautionary Statements

This Current Report on Form 8-K and the corporate presentation include “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, but not limited to, whether or not any patents issue and the scope of future patent or other intellectual property protection, the risk of third-party challenges to the Company’s intellectual property, the likelihood, timing and scope of any future collaborations, the initiation, timing, progress and results of the Company’s current and future preclinical studies and clinical trials, uncertainties related to drug development results, costs and timelines and regulatory risks. Other factors that may cause the Company’s actual results to differ from current expectations are discussed under the caption “Risk Factors” and elsewhere in the Company’s filings and reports with the U.S. Securities and Exchange Commission (“SEC”), including the Company’s Prospectus that forms a part of the Company’s Registration Statement on Form S-1 (File No. 333-217245), which was filed with the SEC pursuant to Rule 424 on May 5, 2017. Except as required by law, the Company assumes no obligation to update any forward-looking statements contained in the corporate presentation to reflect any change in expectations, even as new information becomes available.

<table>
<thead>
<tr>
<th>Exhibit No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.1</td>
<td>Corporate Presentation, dated June 9, 2017</td>
</tr>
</tbody>
</table>
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/ Yaron Werber
   Yaron Werber
   Chief Business and Financial Officer

Dated: June 9, 2017
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This presentation contains projections for Ovid Therapeutics Inc. ("Ovid") and other forward-looking information. Such projections and information are based on assumptions as to future events that are inherently uncertain and subjective. Ovid, its officers, directors or stockholders make no representations or warranties as to the reasonableness of such assumptions or as to whether the future results will occur as projected. It must be recognized that Ovid is an early-stage company and that projections of its future performance are necessarily subject to a high degree of uncertainty, that actual results can be expected to vary from the results projected, and that such variances may be material and adverse. You should and are expected to conduct your own investigation and review of Ovid before determining whether or not to pursue this transaction.

Statements made by Ovid in this presentation may contain certain statements that are forward-looking and involve risks and uncertainties. Words such as "expects," "anticipates," "projects," "estimates," "intends," "plans," "believes," variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are based on current expectations and projections made by management and are not guarantees of future performance. Therefore, actual events, outcomes and results may differ materially from those forward-looking statements include, but are not limited to: whether or not any patents issue and the scope of future patent or other intellectual property protection, the risk of third-party challenges to Ovid's intellectual property, the likelihood, timing and scope of any future collaborations, the initiation, timing, progress and results of our current and future preclinical studies and clinical trials, uncertainties related to drug development results, costs and timelines and regulatory risks. Except as otherwise required under federal securities laws, we do not have any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, changes in assumptions or otherwise.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.
To become a leading rare neurological disorder company

Develop innovative therapies addressing disease-relevant pathways to transform the lives of patients and families

Built on core pillars of value
- Rare disorders with a genetic basis & novel MOA
- Patient-centric approach
- Scalable model

Compelling growth opportunities
- Secure early to late stage assets
- Innovative structures
- Retain US/EU commercial rights

Track record of success
- Deep expertise in translational science, drug evaluation and orphan clinical drug development
- Significant biotech and pharma experience

Pipeline of clinical assets
- Complementary development indications
- Unmet need and first-in-class MOA
Industry Innovators

Jeremy Levin, DPhil, MB BChir
Chairman & CEO

Matthew During, MD, DSc
Director, Founder, President & CSO

Yaron Werber, MD, MBA
Chief Business and Financial Officer & Secretary

Amit Rakhit, MD, MBA
Chief Medical and Portfolio Management Officer

Dirk Haaasner, PhD, MPM
SVP, Global Regulatory Affairs

Claude Nicaise, MD
Head, Strategic Orphan Regulatory Affairs

Suzanne Wakamoto, SPHR, SHRM-SCP
Senior Vice President, Human Resources
## Robust Product Pipeline

<table>
<thead>
<tr>
<th>Indication</th>
<th>Research</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
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<tbody>
<tr>
<td>Angelman Syndrome</td>
<td>OV101</td>
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<tr>
<td>Oral Adult</td>
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<td>Oral Pediatric</td>
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<td>Oral Adolescent</td>
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<tr>
<td>Epileptic Encephalopathies</td>
<td>OV935*</td>
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<td>Oral</td>
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<td>Orphan Epilepsy</td>
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<td>Intravenous</td>
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*Also known as TAK-935. Co-development program with Takeda Pharmaceutical Company Limited pursuant to a license and collaboration agreement.*
Attractive Market Opportunities

Angelman Syndrome
- Prevalence: ~1/12,000 -20,000
- No FDA-approved therapies

Fragile X Syndrome
- Prevalence: 1/3,600-4,000 males
- Prevalence: 1/4,000-6,000 females
- No FDA-approved therapies

Draevet Syndrome
- Incidence: ~1/15,700-20,900 live births
- No FDA-approved therapies

Lennox-Gastaut Syndrome
- Prevalence: ~30,000 adults & children in the US
- No FDA-approved therapies

Tuberous Sclerosis Complex
- Incidence: ~1/6,000 live births
- Prevalence: ~50,000 in the US

OV101

OV935
Our Accomplishments & Key Milestones

**2015**
- In-licensed OV101 from Lundbeck
- Recruited experienced team
- Completed ~$75m series B financing
- Initiated manufacturing validation & fill/finish activities

**2016**
- Submitted IND for adult AS Phase 2 STARS trial & adolescent AS/FXS Phase 1 PK trial with OV101
- Granted Method of Use for OV101
- Granted Orphan Drug Designation for OV101 for the treatment of AS
- Validated API & completed fill/finish activities

**2017+**
- Announced global collaboration with Takeda for OV935
- Initiated Phase 2 OV101 STARS trial
- Initiated Phase 1 OV101 PK trial
- Completed initial public offering
- Initiate Phase 1b/2a trial with OV935 in epileptic encephalopathies
- Phase 1 OV101 PK trial data (H2:17)
- Topline Phase 2 OV101 STARS trial data (2018)

Continue strategic business development activities 2017+

Near-Term Initiatives
OV101

Potentially First-in-Class Therapeutic for
Angelman & Fragile X Syndromes
OV101
δSEGA For Angelman and Fragile X Syndromes

MECHANISM OF ACTION
Potent, δ-selective, extrasynaptic GABA<sub>A</sub> receptor agonist
Validated by clinical data in >4,000 adults with insomnia (approximately 950 patient years of exposure)

PRECLINICAL DATA
Demonstrated ability to restore tonic inhibition and address several key manifestations of AS/FXS

DEVELOPMENT PLAN
Phase 2 STARS trial recruiting adult AS patients
Phase 1 PK trial recruiting adolescents with AS/FXS
Preclinical toxicology ongoing to support pediatric studies

INTELLECTUAL PROPERTY
Portfolio of global polymorph patents to expire in 2025-28
Two U.S. patents for methods of treating AS issued in 2016; due to expire in 2035
Orphan drug designation for OV101 for the treatment of AS granted in 2016

INDICATIONS
Target Neurodevelopment Disorders:
Genetics and Clinical Manifestation

**Angelman Syndrome**

- Monogenetic disorder that silences *UBE3A* gene
  - Developmental delay
  - Impaired motor coordination, seizures/abnormal EEG
  - Sleep and severe speech impairments
  - Anxiety

**No FDA-approved therapies available**

- Current options limited to symptomatic and anti-seizure therapies

**Fragile X Syndrome**

- Monogenetic trinucleotide repeat disorder in the *FMR1* gene
  - Intellectual disability, behavior and language impairments
  - Anxiety and repetitive behaviors

**No FDA-approved therapies available**

- Current options limited to physical, communication, behavior and symptomatic therapy
Tonic Inhibition

Key mechanism in deciphering excitatory & inhibitory neurological signals correctly

Mediated by the δ-subunit containing GABA<sub>A</sub> receptors located extrasynaptically

Impaired tonic inhibition linked to Angelman and Fragile X syndromes

Restoring tonic inhibition improves common symptoms in animal models

Olmos-Serrano et al. J. Neurosci. 2010

Healthy Fragile X Syndrome (Fmr1 KO)

Healthy Angelman Syndrome (Ube3am-/p+)

Tonic Inhibition is Disrupted in Neurological Disorders
Reduced GABA Levels Lead to Loss of Tonic Inhibition in AS and FXS Models

Angelman Syndrome (AS)
- UBE3A Deficiency
- GAT1 does not 'tagged'
- Increased GAT1
- Increased GABA reuptake

Fragile X Syndrome (FXS)
- FMRP Deficiency
- Reduced expression of GAD65/67
- Decreased GABA synthesis
- Decreased GABA release

Decreased Extrasynaptic GABA Levels

Decreased Tonic Inhibition

1. Ubiquitin protein ligase E3A (UBE3A)
2. Fragile X Mental Retardation Protein (FMRP)
OV101 (Gaboxadol)
Distinct Pharmacological Profile

We believe OV101 provides differentiated profile over current options

- Triggers tonic inhibitory signaling
- Potentiates tonic inhibition at nM concentrations

Activity in the presence of low GABA concentrations

Provides pharmacologic compensation for decreased tonic inhibition in AS/FXS mouse models

References:
5. Belelli et al., J. Neurosci. 2005
OV101

Restored Tonic Inhibition & Improved Motor Behavior in AS Mouse Model

Animal model for AS developed:
UBE3A gene-knockout mouse model
Replicates impaired motor function of Angelman Syndrome

In AS mouse model, OV101:
Restored tonic inhibition in cerebellar cells
Improved gait and balance on rotarod
Decreased clasping reflex

OV101
Restored Tonic Inhibition & Improved Motor Behavior in FXS Mouse Model

Fmr1 gene knockout mouse model of FXS:
Electrophysiological studies show loss of tonic inhibition in the amygdala
Mice are hyperactive, show increased sensitivity to “audiogenic” seizures, and reduced performance on learning and memory tasks

In FXS mouse model, OV101:\nRestored tonic inhibition in the amygdala
Improved hyperactivity
Partially normalized response to startling sounds
Improved pre-pulse inhibition (signal-to-noise ratio)

*Olmstead-Dennison et al. Dev. Neuro. 2011
Lundbeck & Merck developed gaboxadol for primary insomnia through Phase 3 trials
Gaboxadol improved sleep architecture with minimal next day residual effects
Over 4,000 adults treated in clinical trials (approximately 950 patient-years of exposure)

Well-tolerated in Phase 2 and 3 insomnia trials
Activity was observed on several sleep metrics versus placebo and relative to active control (Ambien)
Most common adverse events were headache, nausea, vomiting, somnolence and dizziness
Low rate of SAEs observed

Commercial decision not to file NDA after Phase 3 trials were completed in 2007
Overall clinical profile did not support further development
**Phase 1**
PK Trial in Adolescent Subjects with AS/FXS
- n=12
- Age: 13-17 years
- Single dose, open label, PK trial
- Designed to select dosing for future trials

**Phase 2**
Adult Angelman Syndrome Clinical Trial: A Randomized, Double-Blind, Safety and Efficacy Trial of OV101

**Inclusion**
- N=75, age 18-49 years
- Diagnosis of AS

**Exclusion**
- Poorly controlled seizures
- Concomitant disease that would limit participation

**Primary endpoint**
Incidence of adverse events

**Exploratory endpoints**
Clinical Global Impression, Motor Function, Sleep, Behavior, Quality of Life

**Randomization**
- Placebo twice daily
- OV101 twice daily (15 mg night, 10 mg day)
- OV101 once daily (15 mg night)
- Baseline
- Week 12
Our Approach to Rare Epileptic Encephalopathies
Epileptic Encephalopathies

Target rare epileptic disorders typically diagnosed in childhood

Commence in adults with a focus to move to adolescent and pediatric patients

OV935
Novel CH24H Inhibitor for Epileptic Encephalopathies

MECHANISM OF ACTION
Potent (nM), highly selective, cholesterol 24-hydroxylase inhibitor (CH24H)

PRECLINICAL DATA
Anti-seizure activity across several epileptic animal models
24HC potentiates NMDA signaling

DEVELOPMENT PLAN
Initiate a Phase 1b/2a trial in patients with Epileptic Encephalopathies including, Dravet syndrome, Lennox-Gastaut syndrome, and Tuberous Sclerosis Complex in 2017

INTELLECTUAL PROPERTY
Portfolio of issued U.S. and international patents directed to composition-of-matter expiring in 2032

INDICATIONS
### Epileptic Encephalopathies: A Significant Unmet Need

- Typically diagnosed early in life
- Electrographic EEG paroxysmal activity
- Seizures that are usually multiformal and intractable
- Cognitive, behavioral and neurological deficits
- Premature death

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dravet Syndrome</td>
<td>No FDA-approved therapies available. Seizures tend to be refractory to traditional anti-epileptic treatments. 80% have mutated SCN1A gene.</td>
</tr>
<tr>
<td>Lennox Gastaut Syndrome</td>
<td>1-4% of childhood epilepsies. Seizures do not respond well to approved anti-epileptic treatments. Some individuals have de novo mutations, including SCN2A gene.</td>
</tr>
<tr>
<td>Tuberous Sclerosis Complex</td>
<td>60-90% develop seizures during lifetime. Seizures are refractory to traditional anti-epileptic treatments. Most cases caused by de novo mutation of TSC1 or TSC2 genes.</td>
</tr>
</tbody>
</table>
**OV935**

An Innovative Approach to Epilepsy

Potential first-in-class CH24H inhibitor, a target for epilepsy

- Highly selective and potent (nM)
- Favorable pharmacology

**CH24H** predominantly expressed in brain & has a central role in cholesterol homeostasis

Preclinical data demonstrated that inhibition of brain CH24H reduces glutamatergic signaling via NMDA receptors. Preclinical data demonstrated that inhibition of brain CH24H reduces glutamatergic signaling via NMDA receptors. Increased excitatory signaling and activation of NMDA receptors has been implicated in a number of neurological disorders, including epilepsy

![Graph showing changes in 24S-HC levels and NMDA activity](image)

OV935

Anti-Epileptic Effects are Consistent Across Preclinical Models
OV935 shows encouraging activity in acute seizure induction models. Fring’s audiogenic seizure model OV935 treatment resulted in a dose-dependent reduction in seizures, with p < 0.05 ** p < 0.01 *** p < 0.001. The data has been obtained by RIKEN Brain Science Institute, Neurogenetics Laboratory (Lab head: Kazuhiro Yamakawa). Details of the study will be published by RIKEN.
OV935 Shows Activity in Spontaneous Seizure Models

**APP/PS1** transgenic mouse model show electrographic seizures, increases seizure frequency, and mortality.

OV935 treatment significantly prolonged overall survival in APP/PS1 Model.

Mouse viral encephalitis (TMEV) inflammation-induced seizure model

OV935 reduced total number of seizures and number of stage 4/5 seizures.
**OV935**
**Delayed Seizure Development in the PTZ-induced Kindling Mouse Model**

Mice dosed daily with OV935 demonstrated a significant delay in seizure development.
### Four Phase 1 Trials Completed

**86 Healthy Subjects Dosed**

<table>
<thead>
<tr>
<th>Trial 1</th>
<th>Trial 2</th>
<th>Trial 3</th>
<th>Trial 4</th>
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<tbody>
<tr>
<td>Design</td>
<td>Safety and tolerability</td>
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<td>Brain CH24H enzyme occupancy using PET</td>
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<tr>
<td>Phase 1</td>
<td>Design</td>
<td>Phase 1, randomized, double-blind, placebo controlled, single ascending dose</td>
<td>Design</td>
</tr>
<tr>
<td>Subjects</td>
<td>Subjects</td>
<td>Subjects</td>
<td>Subjects</td>
</tr>
<tr>
<td>48</td>
<td>40</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Dosage</td>
<td>Dosage</td>
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</tr>
<tr>
<td>15-1,350mg QD</td>
<td>100-600mg QD, and 300mg BID; 14 days</td>
<td>50-600mg QD</td>
<td>300mg (tab.) QD; 300mg (sol.) QD</td>
</tr>
</tbody>
</table>

Single doses of up to 1,350mg of OV935 were well tolerated.

- In 14-day MAD trial, doses of 100mg, 300mg and 400mg QD were well tolerated.
  - One volunteer at 600mg QD experienced acute psychosis.
  - One volunteer at 300mg QD experienced an event of confusional state.
  - One placebo volunteer reported events of nightmares, spatial disorientation, insomnia, and dizziness.

- All TEAEs resolved with continued dosing through day 15.

Overall no safety issues of concern were identified; no SAEs reported.

---

**Safety and tolerability**

- **Design Phase 1, randomized, double blind, placebo controlled, single ascending dose**
  - **Subjects:** 48
  - **Dosage:** 15-1,350mg QD

- **Design Phase 1, randomized, double-blind, placebo controlled, multiple ascending dose**
  - **Subjects:** 40
  - **Dosage:** 100-600mg QD, and 300mg BID; 14 days

- **Design Open-label, non-randomized**
  - **Subjects:** 11
  - **Dosage:** 50-600mg QD

**Brain CH24H enzyme occupancy using PET**

- **Design Phase 1, randomized, double-blind, placebo controlled, single ascending dose**

**Relative bioavailability (tablet vs. solution); effect of food**

- **Design Phase 1, randomized, open-label, single dose trial**

---

**86 Healthy Subjects Dosed**

Single doses of up to 1,350mg of OV935 were well tolerated.

In 14-day MAD trial, doses of 100mg, 300mg and 400mg QD were well tolerated:

- One volunteer at 600mg QD experienced acute psychosis.
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All TEAEs resolved with continued dosing through day 15.

Overall no safety issues of concern were identified; no SAEs reported.
Dose Dependent Reduction in 24HC Levels Seen in Phase 1

OV935 led to a dose dependent decrease in 24HC levels

Correlation between plasma 24HC and enzyme occupancy (PET) may inform dose selection
FINANCE & BUSINESS DEVELOPMENT

Comprehensive Approach to
Secure Early to Late Stage Assets
Business Development Strategy

- Angelman Syndrome
- Diavet Syndrome
- Fragile X Syndrome
- Tuberous Sclerosis Complex
- Lennox-Gastaut Syndrome
- Dravet Syndrome

Epileptic Encephalopathy
Neurodevelopmental Disorders
Sleep Behavior
Cognition
Motor
Seizures

Late stage preclinical to clinical stage assets
OV101 Agreement with Lundbeck

**Financial Terms with Lundbeck**

- March 2015 exclusive license secured by Ovid
- Global rights
- Extensive patents
- Substantial active pharmaceutical ingredient (API) amounts
- Attractive financial terms to Ovid
  - ~$4M of upfront equity to Lundbeck
  - Up to $181M due to Lundbeck upon achievement of development, regulatory and sales milestones (first payment is $10M due upon successful completion of a Phase 3 trial)
  - Low-to-mid double-digit royalties
Global OneTeam

Global, equal development and commercialization collaboration for OV935 in Epileptic Encephalopathies (EE)

Joint collaboration and governance driven by OneTeam approach for development and commercialization

Ovid leads clinical development and commercial role in US, Europe, Canada and Israel

Ovid to assume regulatory lead following first approval in US, EU and Israel

Takeda received ~$26M in upfront equity

First patient enrolled in first Phase 3 in certain EE triggers milestone to Takeda equal to the lesser of (i) 8% outstanding capital stock or (ii) $50M equity

Takeda eligible for future regulatory and commercial milestones ~$35M

Planning initiation of Phase 1b/2a trial in EE in 2017
Potential to create significant value for patients & stockholders

Building leading company in rare neurological disorders

~$155M in equity financing

Highly experienced management team

Deep expertise in translational science, drug evaluation and orphan clinical drug development

Track record of success in drug development and strategic transactions

Validated expertise with collaborations

Takeda & Lundbeck transactions validates approach and expertise

Two first-in-class assets in a growing pipeline

OV101: Phase 2 trial in adults with AS and Phase 1 trial in adolescents with AS/FXS

OV935: Phase 1b/2a drug candidate for EE

Attractive markets with the opportunity for significant global sales

Targeting novel MOAs that may offer differentiated profiles

Scalable model allows expansion into additional patient populations