# 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) **January 18, 2019**

# CERECOR INC.

(Exact name of registrant as specified in its charter)

**Delaware**
(State or other jurisdiction of incorporation)

| **001-37590** | **45-0705648** |
|---|---|
| (Commission File Number) | (IRS Employer Identification No.) |

**400 E. Pratt Street, Suite 606, Baltimore, Maryland 21202**
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code **(410) 522-8707**

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:

- ☐ 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 (§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 7.01 Regulation FD Disclosure.**

Cerecor Inc. is furnishing presentation materials (the "Investor Presentation") that management intends to use in meetings from time to time with current and potential investors. A copy of the Investor Presentation is attached hereto as Exhibit 99.1.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Cerecor Inc. Investor Presentation. |

SIGNATURE

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.

**CERECOR INC.**

Date: January 18, 2019

/s/ Joseph M. Miller
Joseph M. Miller
Chief Financial Officer

Exhibit 99.1

# Cerecor Corporate Highlights

January 2019

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# Forward-Looking Statements

This presentation may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Cerecor's control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Cerecor's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: our 2018 outlook; the development of product candidates or products; potential attributes and benefits of product candidates; the expansion of Cerecor's drug portfolio, Cerecor's ability to identify new indications for its current portfolio; and new product candidates that could be in-licensed, and other statements that are not historical.

These statements are based upon the current beliefs and expectations of Cerecor's management but are subject to significant risks and uncertainties, including: risks associated with acquisitions, including the need to quickly and successfully integrate acquired assets and personnel; Cerecor's cash position and the potential need for it to raise additional capital; reliance on key personnel, including Mr. Greenleaf; drug development costs and timing (including government shutdowns); and those other risks detailed in Cerecor's filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Cerecor expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Cerecor's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

Cerecor is an integrated biopharmaceutical company developing innovative therapies at the cutting edge of science.

Our pipeline filled with forward-thinking ideas propels us forward.

We are driven to change the lives of patients with rare orphan diseases in pediatrics and neurology.

Driven by Science | Inspired by Hope

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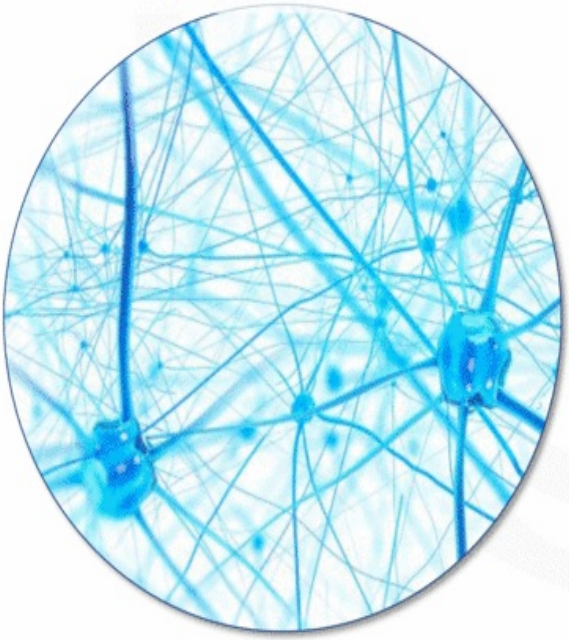
# Focused on Research and Development While Building Our Commercial Capabilities

*Building a Robust Biotech Pipeline of Therapies in Neurology, Pediatric and Orphan Rare Diseases*



*While Developing Commercial Capabilities with our Revenue Producing Pediatric Franchise*

# Corporate Highlights

| | |
|---|---|
| **Innovative Pipeline** | • Emerging clinical & early-stage pipeline<br>• Focus on orphan, neurological & pediatric indications |
| **Commercial Footprint** | • Building a commercial capability<br>• Pediatric franchise generating positive cash flow |
| **Transforming Cerecor** | • Fully-integrated commercial and R&D organization<br>• New management team with proven track record |



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# Overview

1. Management Team
2. Historical Milestones
3. Neurology & Pediatric Rare Disease Pipeline
4. Commercial Pediatric Portfolio
5. Strategic Growth Plans and Outlook
6. Financial Highlights

# Management Team

**Peter S. Greenleaf**
President & CEO

*20+ years industry experience*
- Chairman and CEO, Sucampo Pharmaceuticals
- CEO, Histogenics Corporation
- President, MedImmune Ventures
- Manager, Centocor Biotech (Johnson & Johnson)

**Matthew V. Phillips**
Chief Commercial Officer

*25+ years industry experience*
- President and COO of Zylera Pharmaceuticals
- Executive Director, Victory Pharma
- Director, Eisai Co, Ltd.
- Account Manager, Dura Pharmaceuticals, Inc.

**Joseph Miller**
Chief Financial Officer

*20+ years*
- Vice President of Finance, Sucampo Pharmaceuticals
- Senior Director of Accounting, Qiagen
- Chief Financial Officer, Eppendorf 5Prime
- Certified Public Accountant

**James A. Harrell**
EVP Marketing, Investor Relations

*25+ years industry experience*
- Sr. Vice President | Principal The NSCI Group
- General Manager Specialty Pharmaceuticals, Covidien
- Vice President Marketing Pediatric Infectious Disease, MedImmune
- Sr. Director Marketing IMIDs, Centocor a J&J Company
- Hospital Specialist, ATOD Rhone Poulenc Rorer

**Dr. Pericles Calias**
Chief Scientific Officer

*20+ years industry experience*
- V.P. Global CMC & Development, Sucampo Pharmaceuticals
- CSO, Pharming Group
- Sr. Director Rare CNS Diseases and Device Lead, Shire plc
- Sr. Director Drug Delivery and Chemistry, Eyetech Pharmaceuticals
- Ph.D., Tufts University, Bioorganic Chemistry

**Patrick Crutcher**
VP Business Development

*8+ years industry experience*
- Chairman, President at Ichorion Therapeutics
- SVP, Business Development at Vyera Pharmaceuticals
- BD Analyst at Retrophin
- MSc, CPhil in Statistics, UCLA



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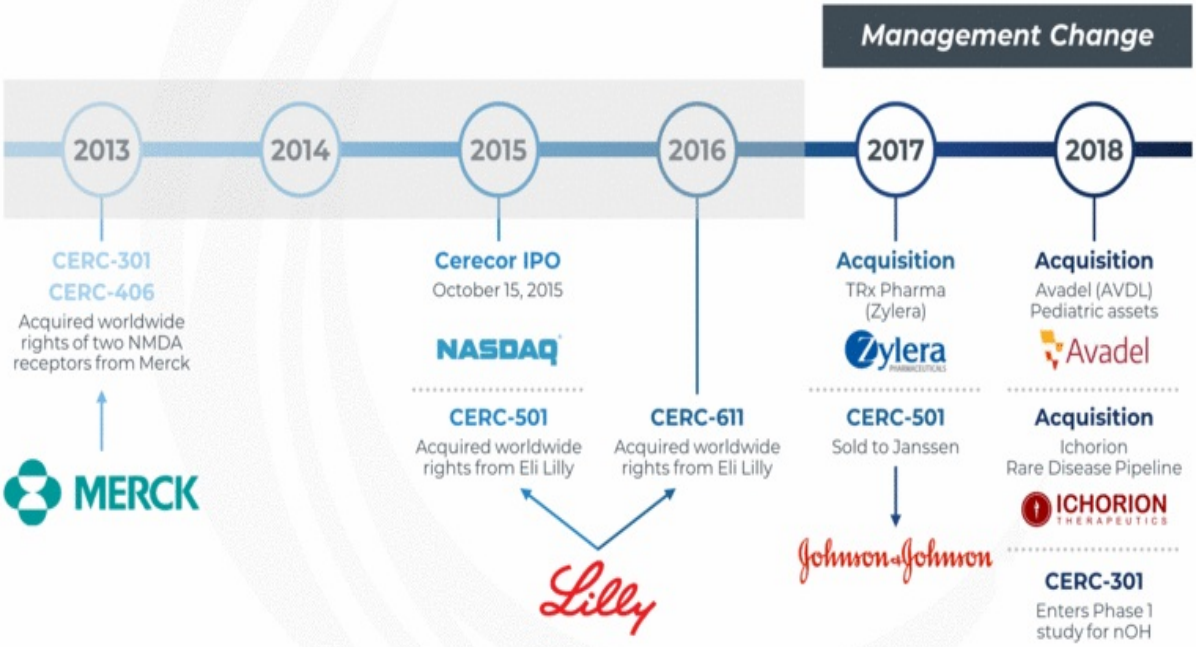
# Historical Milestones



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# Cerecor Evolution

MERCK Lilly

**Neurological Disorders**

**Innovative Approaches to CNS Diseases**

- CERC-301
- CERC-406
- CERC-501
- CERC-611

**In-Licensed CNS Assets**

Zylera PHARMACEUTICALS Avadel

**Pediatric Franchise**

**FDA-Approved Products**

- Poly-Vi-Flor® | Tri-Vi-Flor®
- Karbinal™ ER
- AcipHex® Sprinkle™
- Cefaclor
- Flexichamber™
- Millipred® | Veripred®
- Ulesfia®

**Capability & Cash Flow**

ICHORION THERAPEUTICS

**Pediatric Rare Diseases**

**505(b)(2) Assets & Platform Chemistry**

- CERC-801
- CERC-802
- CERC-803
- CERC-913

**Robust R&D Pipeline**



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# Emerging Clinical & Early-Stage Pipeline

## Each program supported by Clinical Proof-of-Concept

| | | Program | Mechanism of Action | Target Indication | Lead Opt | IND-Enabling | Phase 1 |
|---|---|---|---|---|---|---|---|
| Neurology Division | NCE | CERC-301 | GluN2B selective, NMDA Receptor antagonist | Neurogenic Orthostatic Hypotension (nOH) | | | |
| | | CERC-406 | CNS-targeted, selective COMT inhibitor (2nd Gen) | Motoric and non-motoric symptoms of Parkinson's | | | |
| | | CERC-611 | TARP-γ8 dependent AMPA Receptor antagonist | Partial onset seizures in epilepsy | | | |
| Pediatric Division | 505(b)(2) NCEs | CERC-801 | D-Galactose replacement | PGM1 Deficiency | | | |
| | | CERC-802 | D-Mannose replacement | MPI Deficiency | | | |
| | | CERC-803 | L-Fucose replacement | CDG-IIc | | | |
| | NCE | CERC-913 | Nucleoside replacement | Deoxyguanosine Kinase (DGUOK) Deficiency | | | |

CERC-700(s) Option to develop four additional 505(b)(2) Programs utilizing MicroPump and LiquiTime Dosing Technology are also within the pipeline in conjunction with Avadel Pharmaceuticals in the area of Pediatrics



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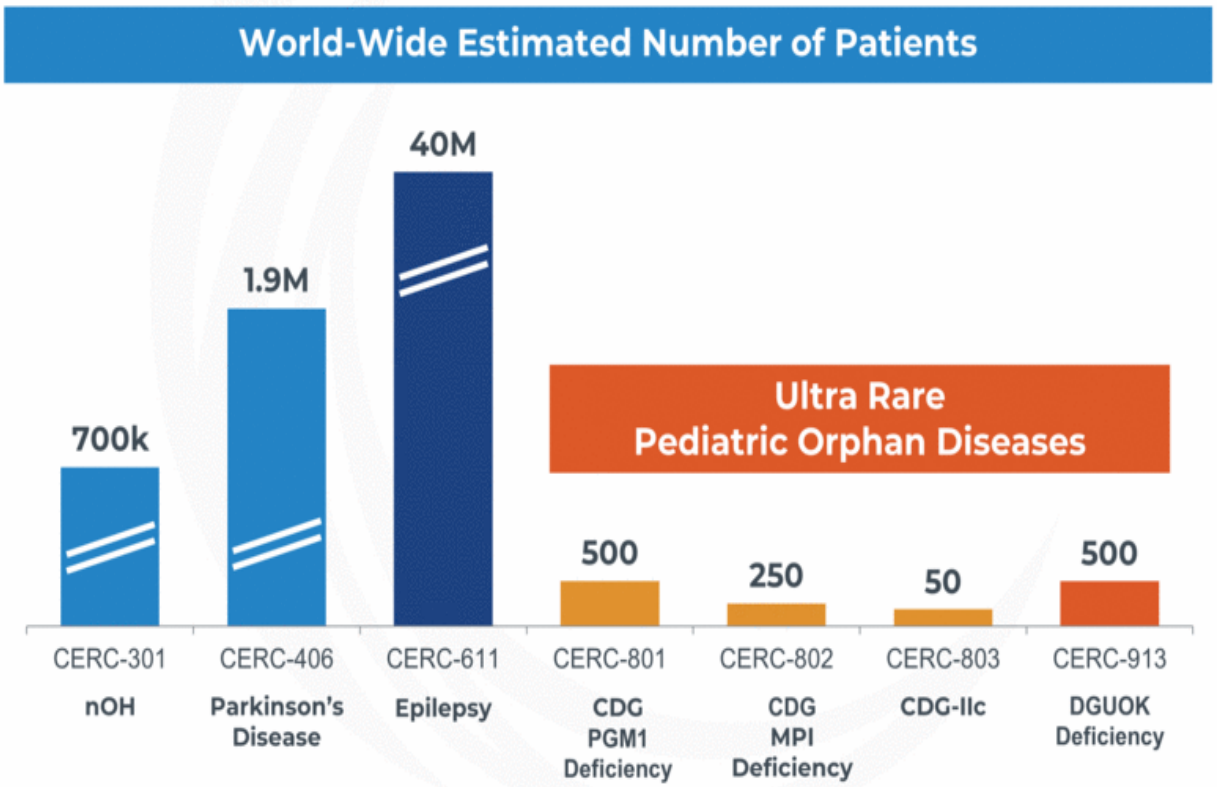
# Market Potential



# R&D Milestones

## Multiple value generating inflection points over next 6 to 12 months

| Neurological Disorders | |
|---|---|
| **CERC-301**<br>Neurogenic Orthostatic Hypotension | Phase I Data 1H19 |
| **CERC-406**<br>Adjunct for Parkinson's Disease | IND Filing 1H20 |
| **CERC-611**<br>Partial onset seizures in epilepsy | In Process |
| **Metabolic Disorders** | |
| **CERC-801***<br>PGMI Deficiency | IND Filing 4Q18 |
| **CERC-802***<br>MPI Deficiency | IND Filing 1H19 |
| **CERC-803***<br>CDG-IIc | IND Filing 2020 |
| **CERC-913**<br>Deoxyguanosine Kinase (DGUOK) Deficiency | IND Filing 2020 |



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# CERC-301

## NR2B selective NMDA receptor antagonist for nOH

**Initiated Phase 1 study of CERC-301 in Parkinson's patients diagnosed with neurogenic Orthostatic Hypotension (nOH)**

### Neurogenic Orthostatic Hypotension (nOH)

- Caused by a failure of the autonomic system to regulate BP upon postural change, increasing risk of falls or injury and decreasing quality of life
- Estimated less than 200,000 patients in the U.S. (ODD eligible)
- Only FDA-Approved therapy is droxidopa; 2018 revs ~$260mm

1 in 5

Parkinson's Patients Experience nOH

nOH is characterized by a sudden drop in blood pressure upon standing



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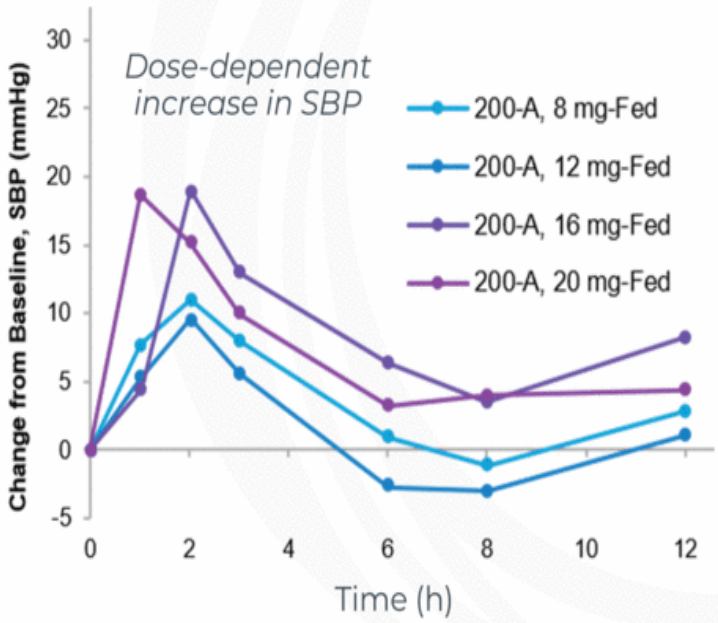
# CERC-301

## NR2B selective NMDA receptor antagonist for nOH

**Multiple exposures in >375 subjects, providing robust safety data & blood pressure effect**

### Clin301-200-A




### Target Product Profile

- Long-term clinical benefit
- Rapid onset of action
- Superior safety profile than midodrine
- Use as stand-alone or adjunctive with existing nOH therapies

Note: Clin301-200-A data from Phase I HV Study (a normotensive population)



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# CERC-301
# NR2B selective NMDA receptor antagonist for nOH

## Opportunity to rapidly demonstrate proof-of-concept in patients

| Phase 1 SAD in PD patients with nOH | |
|---|---|
| **Enrollment** | • 12 active centers in US |
| **Design** | • N = 20 (8, 12, 16 & 20 mg)<br>• Double-blind, randomized, pbo-controlled<br>• Interim Analysis at 10 patients |
| **Endpoints** | • Safety, Tolerability & PK<br>• BP measurement<br>• Symptomatic assessment |

| | Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5[a] |
|---|---|---|---|---|---|
| **Arm 1** (n = 5) | pbo | 8 mg | 12 mg | 16 mg | 20 mg |
| **Arm 2** (n = 5) | 8 mg | pbo | 12 mg | 16 mg | 20 mg |
| **Arm 3** (n = 5) | 8 mg | 12 mg | pbo | 16 mg | 20 mg |
| **Arm 4** (n = 5) | 8 mg | 12 mg | 16 mg | pbo | 20 mg |

- 5 visits, 7 to 10 days apart; 4 single escalating doses of CERC-301 or placebo
- Assess safety, tolerability, effect on blood pressure & PK
- Patients will complete a standardized Orthostatic Standing Test and symptomatic assessment (OHSA Item #1) at each visit



[a] Randomized 4:1

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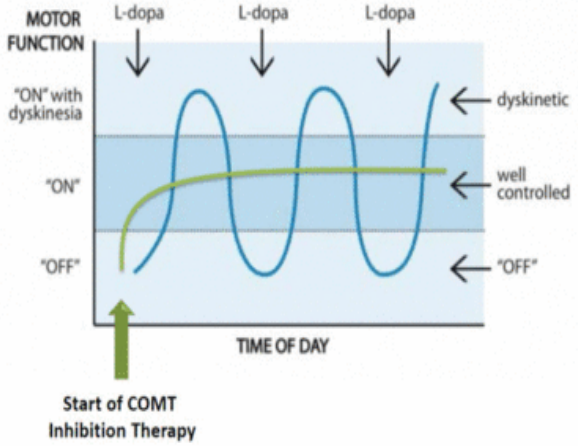
# CERC-406
## COMT inhibitor for Parkinson's Disease

### 2nd generation, CNS-selective COMT inhibitor to enhance efficacy and minimize toxicity seen with 1st generation therapies

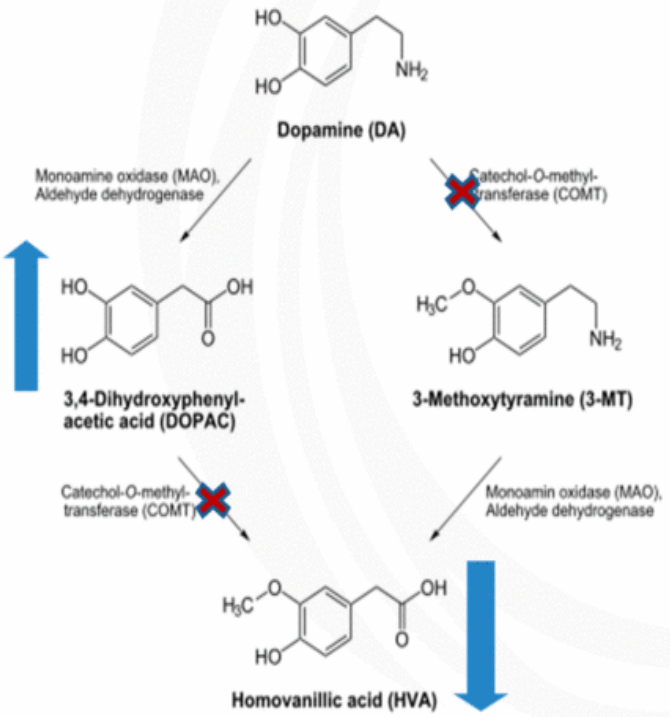
- Dopamine "replacement" therapy can effectively control PD symptoms, but over time patients may begin to experience "on/off" episodes associated with motor and non-motor symptoms
- COMT inhibitors change levodopa pharmacokinetics by increasing its systemic availability and decreasing its elimination allowing for tighter control of dopamine levels keeping it within the therapeutic window




- Peripherally-restricted COMT inhibitors have been used for decades as a key component of PD therapy, but unfortunately have undesirable side effects and lack brain penetration

# CERC-406
## COMT inhibitor for Parkinson's Disease – Our Lead Candidate

**Biomarkers for translational proof-of-concept with promising drug properties**




- High specificity for COMT expressed in the CNS
- Good oral bioavailability & brain penetration
- Acceptable PK profile in rat & dog
- Low potential for drug to drug interactions

# CERC-611

## TARP-γ8 dependent AMPA receptor antagonist for partial onset seizures

**Phase 1-ready candidate with therapeutic potential for partial onset seizures in patients with epilepsy**

### Significant Unmet Need

- Epilepsy affects over 65 million patients worldwide
- 30%-40% of patients refractory; high degree of poly-pharmacy common
- All anti-seizure drugs have side effects (e.g. motoric) limiting use and the timely achievement of therapeutic dose levels

### Unique Mechanism of Action

- AMPA receptors mediate fast synaptic neurotransmission within the CNS and are a proven target for anti-seizure efficacy
- CERC-611 is the first known AMPA receptor antagonist that selectively targets the hippocampus
- CERC-611 shows lack of motoric impairment at efficacious exposures in animal models of epilepsy

***Ongoing conversations with the FDA regarding appropriate dosing regimen***



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# Ichorion Acquisition

**All stock ($26M) transaction announced on September 25th, 2018**

## Strategic, Clinical & Commercial Fit to Accelerate Transformation

| | |
|---|---|
| Private biopharma focused on therapies for ultra-rare pediatric diseases | White-space opportunity that compliments Cerecor's existing commercial footprint & pipeline |
| 3 accelerated development programs utilizing the 505(b)(2) pathway | Fast to market, low development costs (<$10M/program) & PRV eligibility |
| Low cost-of-capital to launch products in the US independently | Small academic sales specialists, MSLs & reimbursement team in rare diseases |



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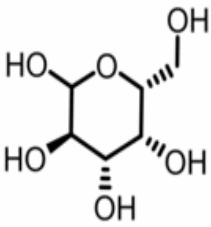
# CERC-800s

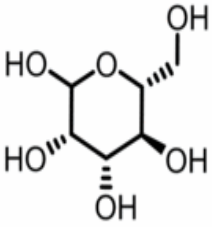
## Substrate replacement therapies for CDGs

**Oral, small molecule, naturally occurring monosaccharides used as standards-of-care for Congenital Disorders of Glycosylation (CDGs)**

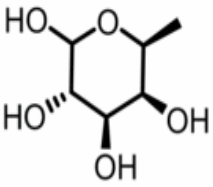
- More than 100 CDGs identified to date




D-Galactose




D-Mannose




L-Fucose

| Eligibility | CERC-801 | CERC-802 | CERC-803 |
|---|---|---|---|
| 505(b)(2) NDA Pathway | ✓ | ✓ | ✓ |
| NCE 5-yrs Exclusivity | ✓ | ✓ | ✓ |
| ODD 7-yrs Exclusivity | ✓ | ✓ | ✓ |
| Priority Review Voucher | ✓ | ✓ | ✓ |
| EMA ODD 10-yrs Exclusivity | ✓ | ✓ | ✓ |



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# CERC-800s

## Substrate replacement therapies for CDGs

**Monogenic disorders resulting in glycosylation defects with broad clinical spectrum, including life-threatening complications**

| | |
|---|---|
| **CERC-801** | **Multi-system disease manifestation in PGM1-CDG**<br>*D-Galactose leads to significant improvement in key clinical symptoms* |
| **CERC-802** | **Life-threatening gastrointestinal disorder in MPI-CDG**<br>*D-Mannose rapidly resolves hematological & intestinal abnormalities* |
| **CERC-803** | **Immunodeficiency with CNS impairment in SLC35C1-CDG**<br>*L-Fucose normalizes cell counts & reduces infection risk* |

**Ultra-orphan IEMs with serious and life-threatening medical needs**

- <500 patients WW per indication
- High pediatric morbidity & mortality
- No approved treatments
- Documented efficacy & safety
- Clinical symptoms improve rapidly
- Reduced nonclinical requirements



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# CERC-800s
## Substrate replacement therapies for CDGs

### CERC-800s development framework leveraging 505(b)(2) pathway

**Secure use rights for KOL clinical datasets**

- Primary data strengthen regulatory submissions

**Leverage published literature to demonstrate efficacy & safety**

- Clinical & nonclinical data available to support all three programs
- Build scientific bridge to published literature

**Sponsor-initiated retrospective & prospective studies to generate data sets unique from those publicly available**

- Confirmation of efficacy & safety, Natural History

**Clinical focus on addressing gaps in product label**

- Prospective PK & Safety combined with Chart Review to facilitate approval

# CERC-800s
## Substrate replacement therapies for CDGs

**Retrospective chart reviews & registry data create opportunity to minimize or obviate prospective clinical studies**

| Developer | Therapeutic (Indication) | Pivotal Study Strategy |
|---|---|---|
| RECORDATI | Carbaglu (NAGS Deficiency) | Retrospective case series summary (13/23 patients with complete data) & 3 patients treated prospectively (2010) |
| ASKLEPION PHARMACEUTICALS, LLC | Cholbam (Bile Acid Disorders) | Case report form from retrospective chart review of patients in open-label, single-arm Expanded Access Protocol (2015) |
| Provepharm | ProVay Blue (Acquired Methemoglobinemia) | Retrospective case reports from a multicenter chart review in addition to cases found in published literature (2016) |
| VERTEX | Kalydeco (Cystic Fibrosis) | Expanded label (from 10 mutations to 33) based on registry data & mechanistic information from lab studies (2017) |
| genzyme | Lumizyme (Pompe Disease) | Reference to survival data from an international registry of infantile-onset disease demonstrating mortality benefit (2010) |

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CDG Connect Patient Insights Network (PIN)
https://connect.invitae.com/org/cdg



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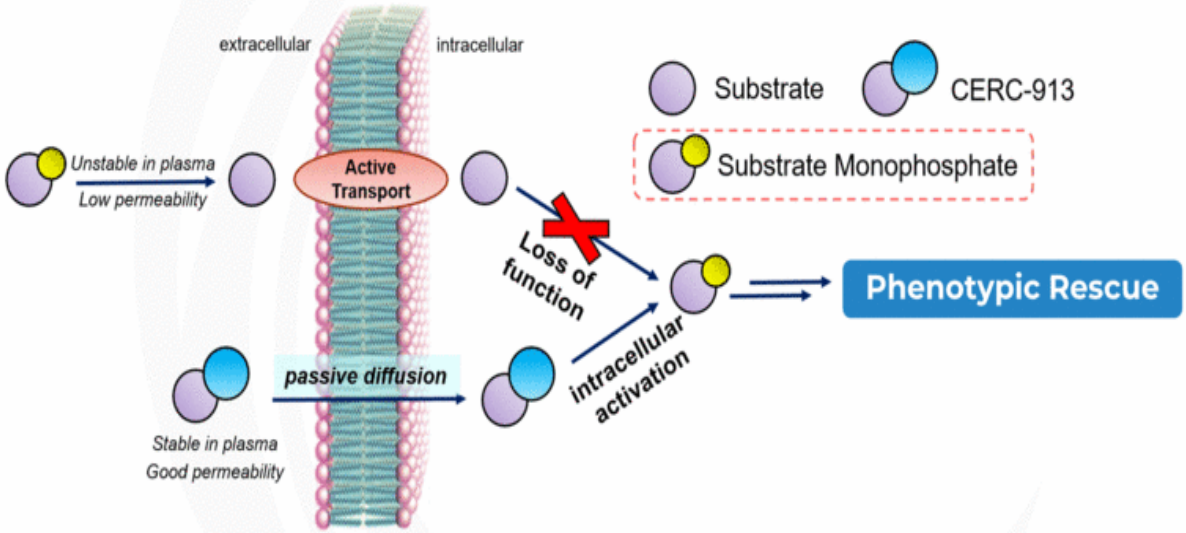
# CERC-913

## ProTide Nucleotide for Deoxyguanosine Kinase (DGUOK) Deficiency

**Overcome key limitations of direct substrate replacement: stability, permeability & kinase bypass**




### CERC-913 Attributes

- Proof-of-concept in patient-derived & animal-based disease models
- ProTide similar to advanced clinical candidates & approved drugs
- Metabolite ID & PK profile in dog support translational PKPD



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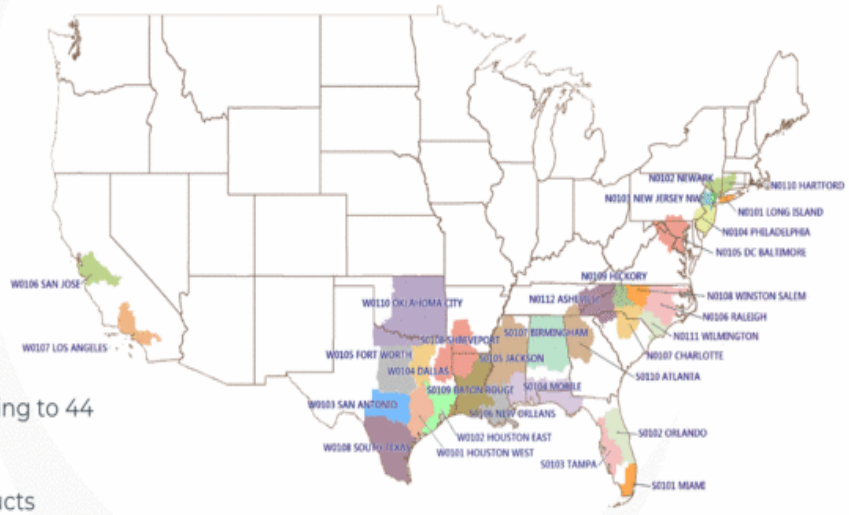
# Overview

1. Management Team
2. Historical Milestones
3. Neurology & Pediatric Rare Disease Pipeline
4. **Commercial Pediatric Portfolio**
5. Strategic Growth Plans and Outlook
6. Financial Highlights

# Building Commercial Capabilities in Pediatrics

## ~50% of the Overall Market Potential Covered with 32 Territories Sales Force Expansion Underway to Increase SOV

- 1 Chief Commercial Officer
- 1 EVP Marketing & Investor Relations
- 1 Director of Sales
- 3 Regional Sales Managers
- 1 Director of Sales Training and Operations
- 1 Director of Trade Sales and Operations
- 1 Institutional Sales Manager
- 1 Sales Analyst
- 32 Territory Managers Expanding to 44




- 3 Focused / 8 Promoted Products
- Territory Expansion Underway
- Cloud-based CRM System
- Novel SICP

# Pediatric Franchise with Eight Product Lines

## Zylera Pharmaceuticals

Millipred® Tablets
(prednisolone USP, 5 mg)

Poly-Vi-Flor®

Tri-Vi-Flor™

ulesfia®
(benzyl alcohol) Lotion 5%

## Avadel Pediatric Assets

AcipHex® Sprinkle™
(rabeprazole sodium)
Delayed-Release
Capsules

CEFACLOR
For Oral Suspension, USP
125 mg/5 mL • 250 mg/5 mL • 375 mg/5 mL

Karbinal ER
(carbinoxamine maleate) extended-release
oral suspension | 4mg/5mL

Oflexichamber®
Anti-static Valved Collapsible Holding Chamber ℞ Only



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# Why Pediatrics?

## Pediatrics Represents a Focused, Defined and Specific Patient Population Treated by One Specialty Segment

**Our Existing Pediatric Product Portfolio Treats Nearly 75% of the Top 25 Pediatric Diagnosis Codes**

### Top 25 Pediatric Codes 2013 AAP Pediatric Coding Newsletter[1]

1. Routine Child Health Examination
2. Acute Upper Respiratory Infection
3. Otitis Media
4. Acute Pharyngitis
5. Asthma
6. Follow-up Exam
7. Allergic Rhinitis
8. Sinusitis
9. Dermatitis
10. Attention-Deficit/ Hyperactivity Disorder
11. Cough
12. Viral Infection
13. Streptococcal Sore Throat
14. Bronchitis
15. Conjunctivitis
16. Esophageal Reflux
17. Influenza with Respiratory Manif.
18. Gastroenteritis / Colitis
19. Fever
20. Constipation
21. Vaccination
22. Abdominal Pain
23. Viral Diseases
24. Pneumonia

*ICD-10-CM* codes are displayed as 24 code categories that include the 25 diagnoses from the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) list (2 otitis media codes were included in ICD-9-CM).



1. AAP pediatric coding newsletter coding.aap.org August 2013

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# Net Product Sales

## Net Product Sales Last 4 QTR Trend (in $000's)


FY18 Net Sales Guidance = $18 to $20 million

# Balance Sheet

## Cash Trend Analysis (in $000's)


## Total Assets Trend Analysis (in $000's)

# 2019 Growth Plans

## 1 Advance Pipeline

CERC-301

CERC-406

CERC-611

CERC-801

CERC-802

CERC-803

CERC-913

## 2 Build Commercial Excellence

Grow Market Share

Expand Commercial Footprint

## 3 Accelerate Business Development Activity

Acquire/in-license commercial-ready or marketed asset(s)

Acquire/in-license complimentary pipeline assets



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NASDAQ:CERC
www.cerecor.com
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# Driven by Science

# Inspired by Hope

CERECOR