# 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) July 10, 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.)** |

**540 Gaither Road, Suite 400, Rockville, Maryland 20850**
**(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. ☒

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.001 Par Value | CERC | Nasdaq Capital Market |

**Item 7.01. Regulation FD Disclosure.**

On July 10, 2019, Cerecor, Inc. posted an updated Investor Presentation to its website at www.cerecor.com. A copy of the presentation slides 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: July 10, 2019

/s/ Joseph M. Miller

Joseph M. Miller

Chief Financial Officer

Exhibit 99.1

# Cerecor Corporate Highlights

July | 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 2019 outlook; the development of product candidates or products; timing and success of trial results and regulatory review (including as it may be impacted by government shut-downs); potential attributes and benefits of product candidates; the expansion of Cerecor's drug portfolio; 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: reliance on and the need to attract, integrate and retain key personnel; drug development costs, timing and other risks; Cerecor's cash position and the potential need for it to raise additional capital; risks associated with acquisitions, including the need to quickly and successfully integrate acquired assets and personnel; 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.



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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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# Cerecor Today

## Focused on Advancing R&D, while Optimizing Commercial Capabilities

| | |
|---|---|
| **Innovative Pipeline** | • Emerging clinical & early-stage pipeline<br>• Three 505(b)(2) programs with expedited path to NDA<br>• Focus on orphan, neurological & pediatric diseases |
| **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 |

# Overview

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

# Management Team

## Extensive experience in development and commercialization

**Dr. Simon Pedder**
Executive Chairman of the Board

*30+ years industry experience*
- President and CEO of Chelsea Therapeutics
- Chief Business and Strategy Officer, Proprietary Products at Athenex
- President and CEO of Cellectar Biosciences
- Vice President of Oncology Pharma Business at Hoffmann-LaRoche
- Faculty Department of Pharmacology College of Medicine, University of Saskatchewan

**Patrick Crutcher**
Chief Strategy Officer

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

**Joseph Miller**
Chief Financial Officer

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

**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.

**Dr. Pericles Calias**
Chief Scientific Officer & Head of R&D

*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

**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



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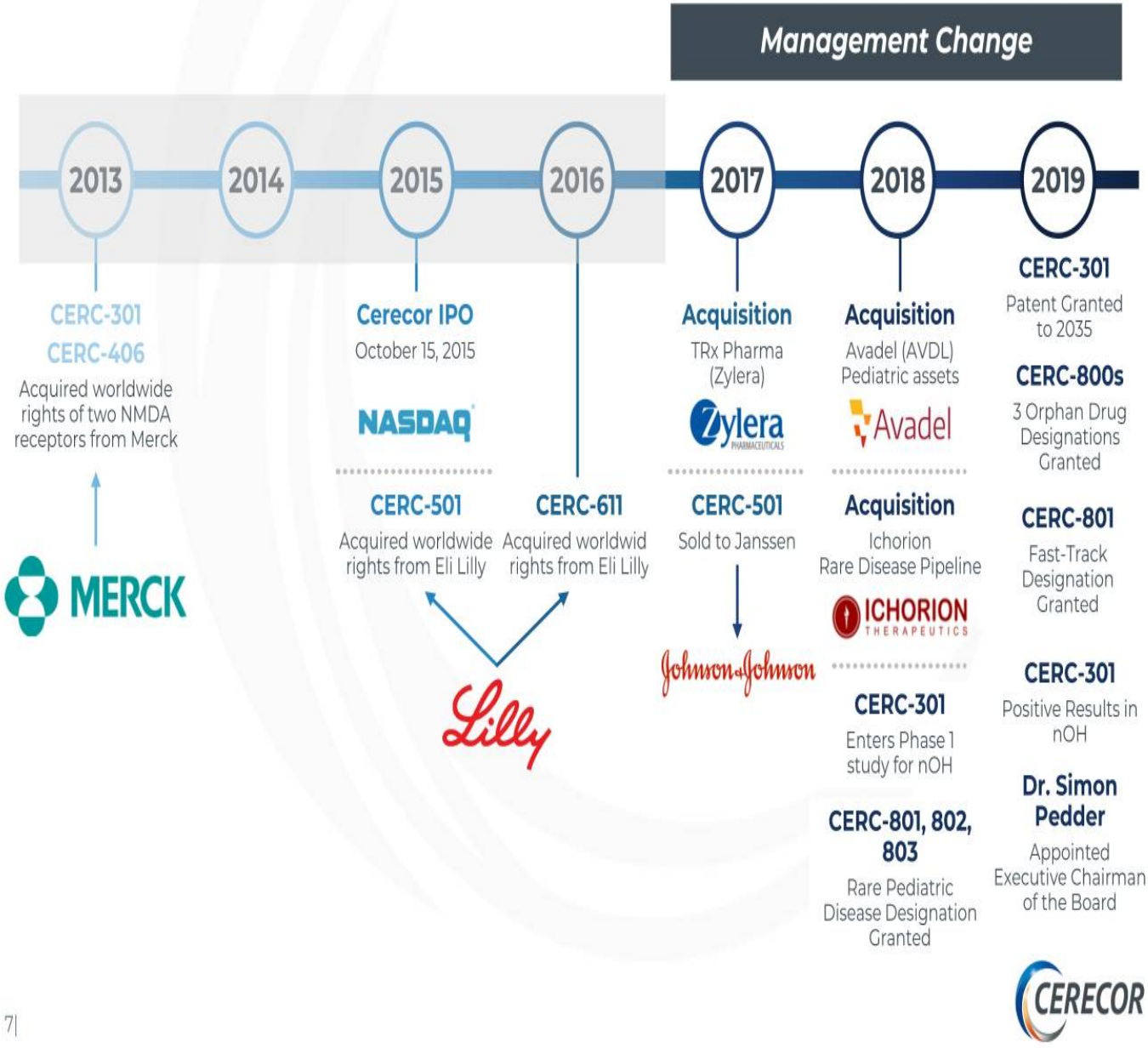
# Historical Milestones



# Cerecor Evolution

MERCK Lilly › Zylera PHARMACEUTICALS Avadel › ICHORION THERAPEUTICS

| Neurological Disorders | Pediatric Franchise | Pediatric Rare Diseases |
|---|---|---|
| **Innovative Approaches to CNS Diseases** | **FDA-Approved Products** | **505(b)(2) Assets & Platform Chemistry** |
| • CERC-301<br>• CERC-406<br>• CERC-501<br>• CERC-611 | • Poly-Vi-Flor® \| Tri-Vi-Flor®<br>• Karbinal® ER<br>• AcipHex® Sprinkle™<br>• Cefaclor<br>• Flexichamber™<br>• Millipred® \| Veripred®<br>• Ulesfia® | • CERC-801<br>• CERC-802<br>• CERC-803<br>• CERC-913 |
| **In-Licensed Pipeline CNS Assets** | **Capability & Cash Flow** | **Robust Orphan Rare Disease Pipeline** |



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# Emerging Clinical & Early-Stage Pipeline

| | Program | Mechanism of Action | Target Indication | Development Stage |
|---|---|---|---|---|
| Metabolic Disorders | CERC-801 | D-Galactose replacement | PGM1 Deficiency | *Phase 1* *505(b)(2)* |
| | CERC-802 | D-Mannose replacement | MPI Deficiency | *IND-Enabling* *505(b)(2)* |
| | CERC-803 | L-Fucose replacement | SLC35C1-CDG (CDG-IIc) | *IND-Enabling* *505(b)(2)* |
| | CERC-913 | Nucleoside replacement | DGUOK Deficiency | Pre-Clin POC |
| Neurology Disorders | CERC-301 | GluN2B selective, NMDA Receptor antagonist | Neurogenic Orthostatic Hypotension | Phase 1 |
| | CERC-406 | CNS-targeted, COMT inhibitor (2nd Gen) | Parkinson's Disease | IND-Enabling |
| | CERC-611 | TARP-γ8 dependent AMPA Receptor antagonist | Partial Onset Seizures | Phase 1 Ready |

*Denotes Pediatric Program and Expedited 505(b)(2) Approval Pathway*

**Denotes Pediatric Program**

**Denotes Neurology Program**



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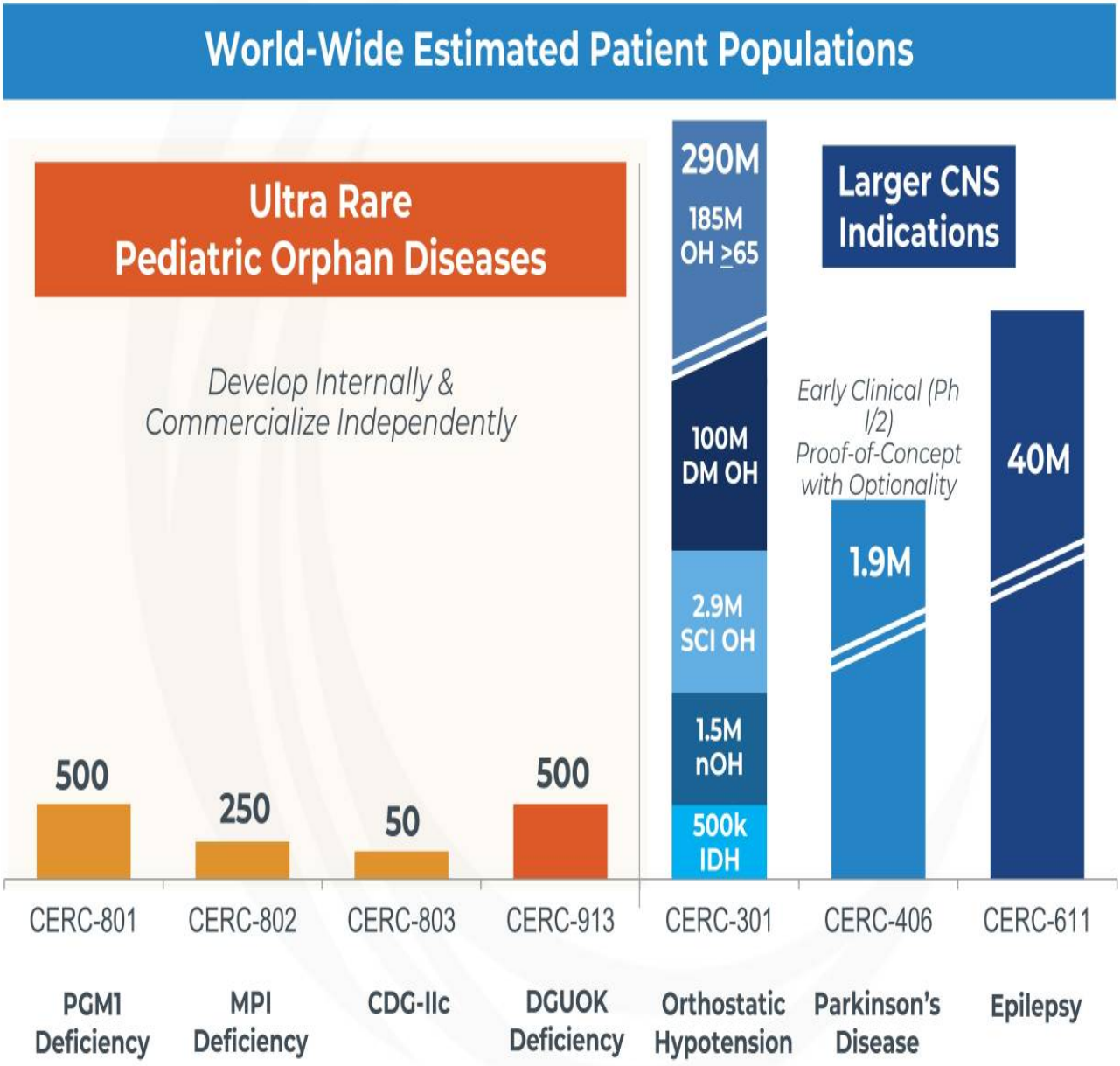
# Market Potential




IDH- Intra-Dialytic Hypotension; nOH- Neurogenic Orthostatic Hypotension; SCI- Spinal Cord Injury; DM- Diabetes Mellitus

# R&D Milestones

## Multiple value generating inflection points over next 12 to 18 months

| | Program | Target Indication | Upcoming Milestone |
|---|---|---|---|
| Metabolic Disorders | CERC-801* | PGM1 Deficiency | FDA Discussion - 2H19 |
| | CERC-802* | MPI Deficiency | IND Acceptance – 2H19 |
| | CERC-803* | SLC35C1-CDG (CDG-IIc) | IND Filing - 2020 |
| Neurology Disorders | CERC-301 | Neurogenic Orthostatic Hypotension | MOA Study / Evaluate Additional Indication(s) 2H19 |
| | CERC-406 | Parkinson's Disease | IND Filing - 1H20 |
| | CERC-611 | Partial Onset Seizures | Under Strategic Review |

*505(b)(2) Pathway



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# Pediatric Rare Disease Portfolio

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# Congenital Disorders of Glycosylation (CDGs)

## Orphan diseases with an estimated prevalence of 1 in 100,000

- Genetic diseases that result in impaired glycoprotein production and function
- Glycoproteins are critical for cell structure and function, particularly for circulating proteins and enzymes such as hormones and coagulation factors
- Improper sugar architecture diminishes and/or disrupts protein function
- Patients typically have multi-organ dysfunction, some with nervous system involvement, including: structural abnormalities, myopathies, coagulopathies, hypoglycemic episodes, epileptic seizures and developmental delay
- High morbidity and mortality diseases with approximately 25% childhood mortality

# 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 Deficiency**<br>*D-Galactose leads to significant improvement in key clinical symptoms* |
| **CERC-802** | **Life-threatening gastrointestinal disorder in MPI Deficiency**<br>*D-Mannose rapidly resolves hematological & intestinal abnormalities* |
| **CERC-803** | **Immunodeficiency with CNS impairment in CDG-IIc**<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



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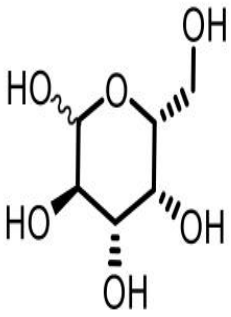
# CERC-800s

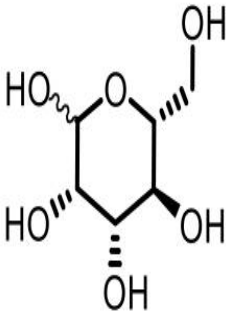
## Substrate replacement therapies for CDGs

**Oral, small molecule, naturally occurring monosaccharides used as standards-of-care for CDGs**

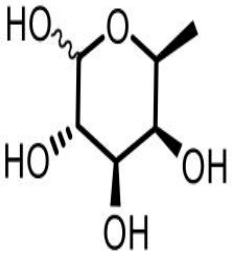
- Safe
- Efficacious
- Rapid Onset of Action




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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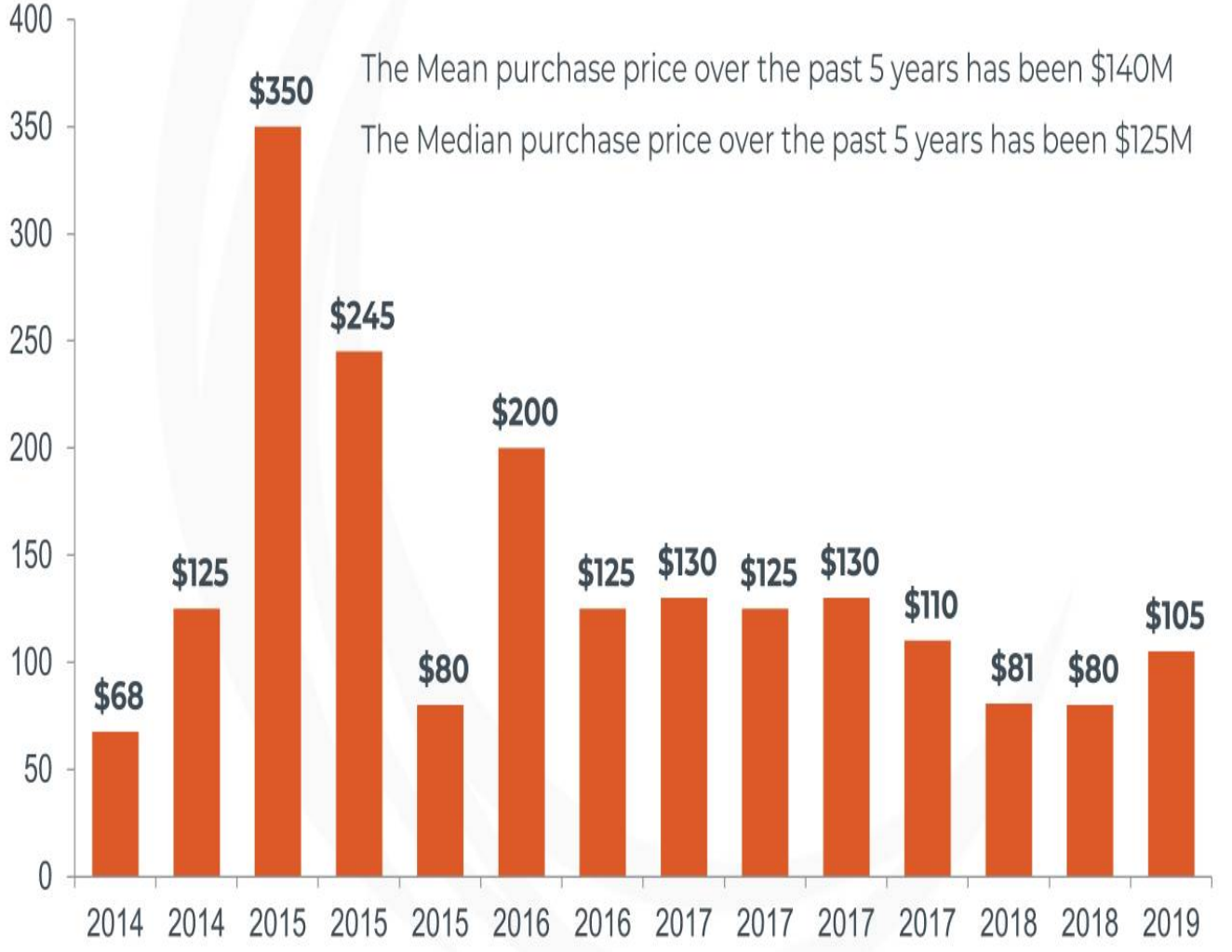
# The Value of a Pediatric Review Voucher

## PRV Sales to Date with Purchase Amount






Reference: https://priorityreviewvoucher.org/ downloaded April 24, 2019

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# CERC-800s

## Substrate replacement therapies for CDGs

**Retrospective chart reviews & registry data have been successfully used 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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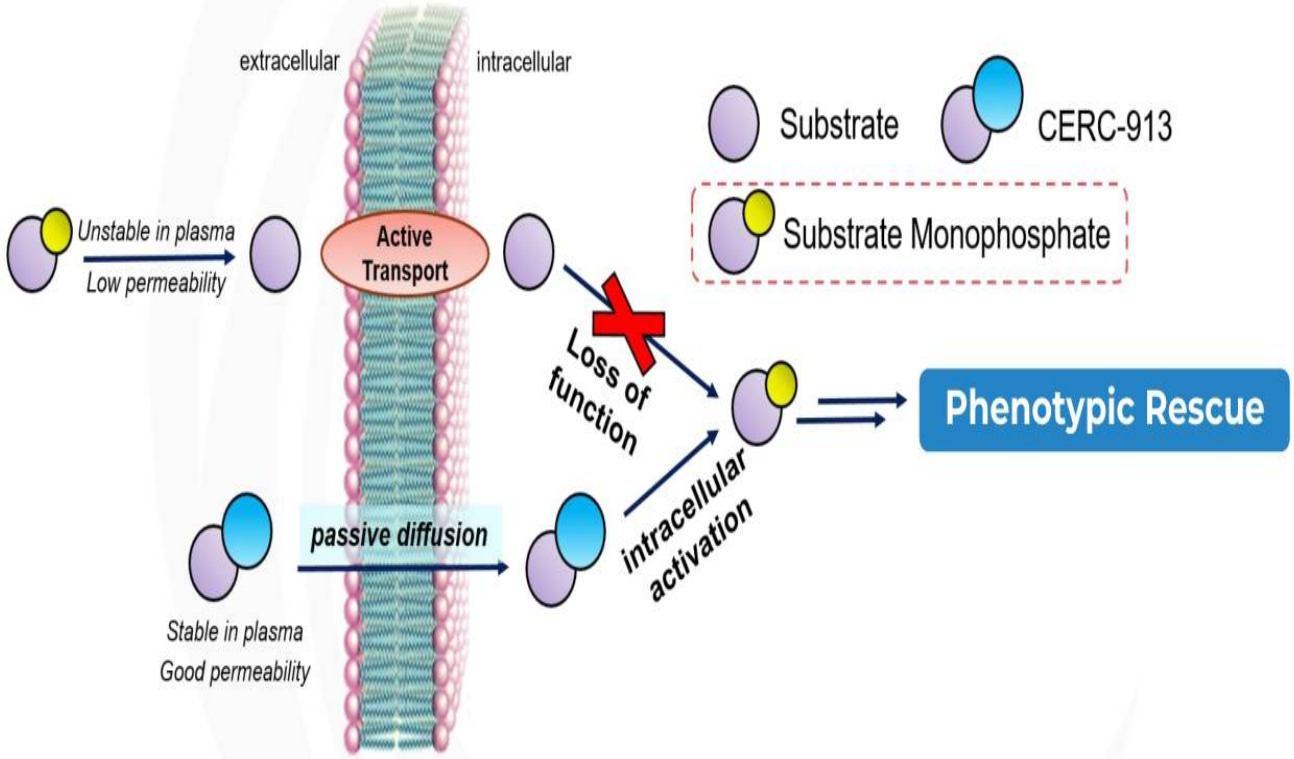
# CERC-913

## 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
- Potential for PRV eligibility



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# Neurology Disorders

# CERC-301

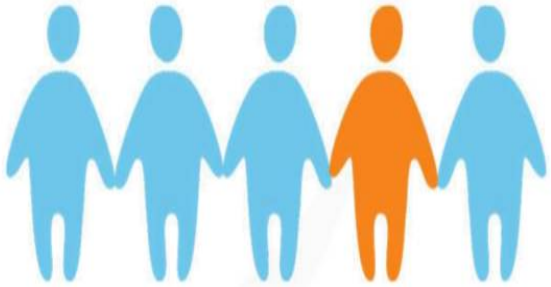
## NR2B selective NMDA receptor antagonist for nOH

**Autonomic nervous system fails to regulate vasoconstriction due to underlying neurological disease**

- Rapid and significant (20mm Hg) drop in blood pressure caused by postural change
- Increased risk of falls or injury, leading to decreased quality of life
- Estimated approximately 300,000 patients in the U.S. and 1,500,000 world-wide
- Single FDA-Approved therapy, Northera® (droxidopa)
  - Effectiveness beyond 2 weeks of treatment has not been established
  - Significant proportion of non-responders (>1/3 in pivotal study)
  - 2018 revs ~$210mm[1]

**1 in 5**

***Parkinson's Patients Experience nOH***





1. Lundbeck 2018 Annual Report

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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 & PK
- Measure BP effects during orthostatic challenge(s)
- Symptomatic assessment (OHSA Item #1) at each visit



[a] Randomized 4:1

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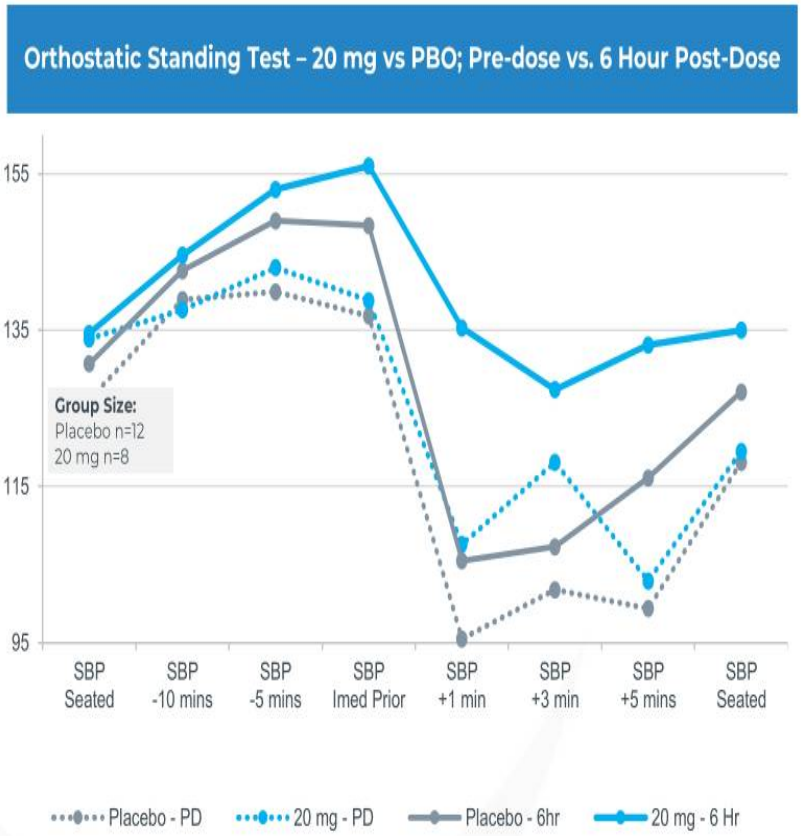
# CERC-301

## NR2B selective NMDA receptor antagonist for nOH

## Positive Phase I results depict a rapid, robust and sustain increase in Systolic Blood Pressure in Parkinson's Patients with nOH

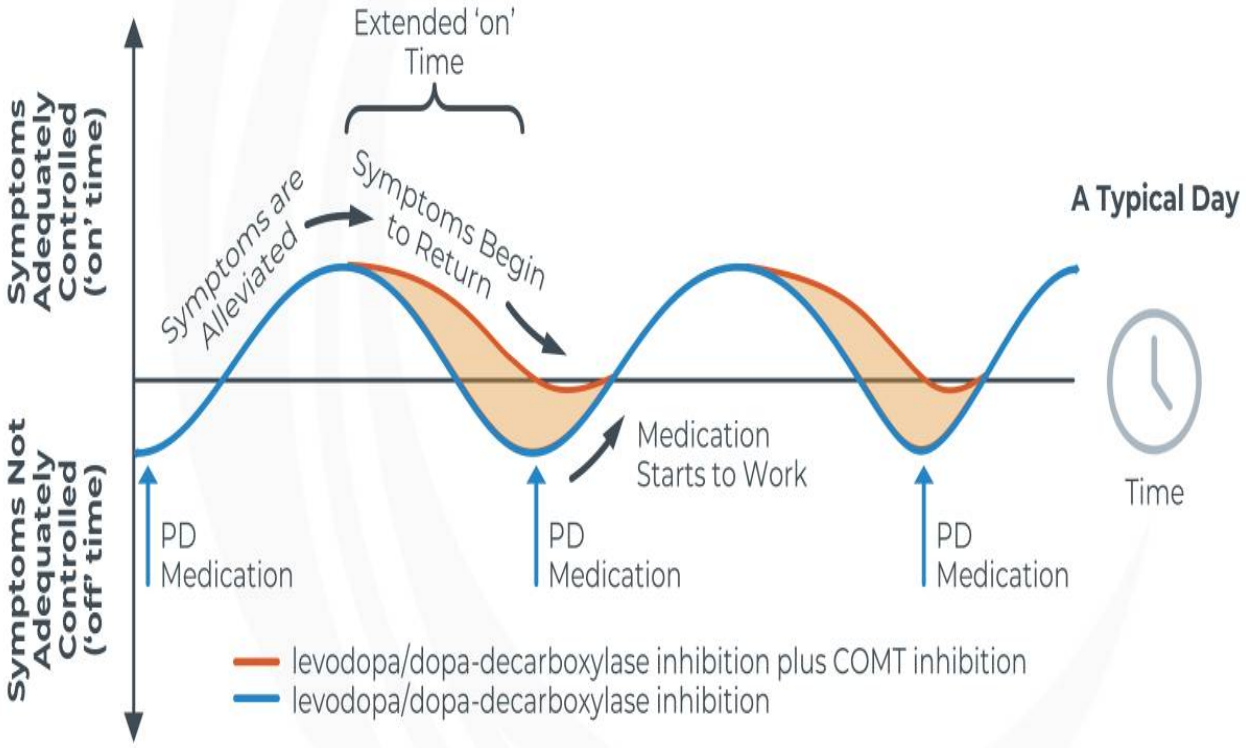
- Top-line results demonstrate rapid, sustained and clinically meaningful increases in systolic blood pressure (SBP) from baseline to 6 hours
- 20mg dose demonstrated a 15.2 mmHg increase in SBP at 1-hour
- 20mg dose reached 29.1 mmHg from baseline to 4 hours
- The early and sustained effect may differentiate CERC-301 from existing nOH / OH treatments
- All doses tested were safe and well tolerated with no serious adverse events reported



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

**Next generation, CNS-penetrant COMT inhibitor to enhance efficacy and minimize toxicity seen with 1st generation therapies**

- As PD progresses the therapeutic window of L-Dopa becomes smaller, increasing the on/off periods




**COMT inhibitors are taken with levodopa to reduce off-time and increase on-time without dyskinesia**

 Figure Source: European Parkinson's Disease Association (EPDA)

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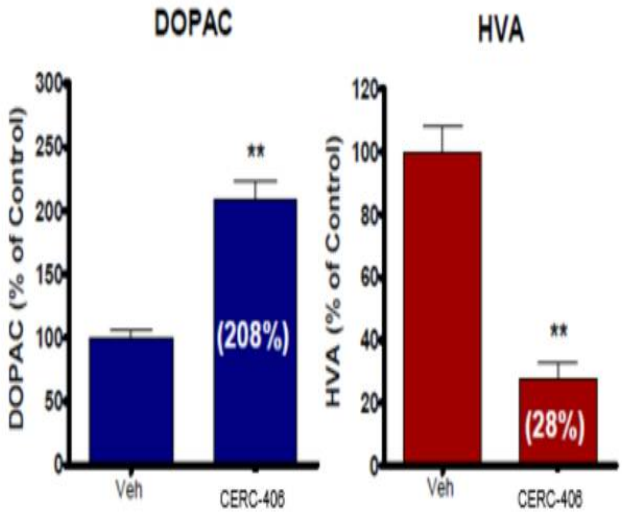
# CERC-406
## COMT inhibitor for Parkinson's Disease

### COMT inhibition provides an *in vivo* biomarker for target engagement by measuring DOPAC and HVA

- COMT regulates dopamine (levodopa) breakdown via the conversion of dihydroxyphenyl-acetic acid (DOPAC) to homovanillic acid (HVA)

| 1st Gen COMT Inhibitors | Drawbacks / Marketing Status |
|---|---|
| Tolcapone | black box warning generic |
| Entacapone | peripherally-restricted generic |
| Opicapone | peripherally-restricted *NDA 1H19** |

**CSF Biomarkers: Single, 100 mg/kg CERC-406 dose in rats**




 *Projected

# 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

***Under Strategic Review***



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# Commercial Pediatric Portfolio

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# Building Commercial Capabilities in Pediatrics

## Eight commercial products promoted across 42 U.S. Territories

Millipred® Tablets (prednisolone USP, 5 mg)

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

Poly-Vi-Flor®

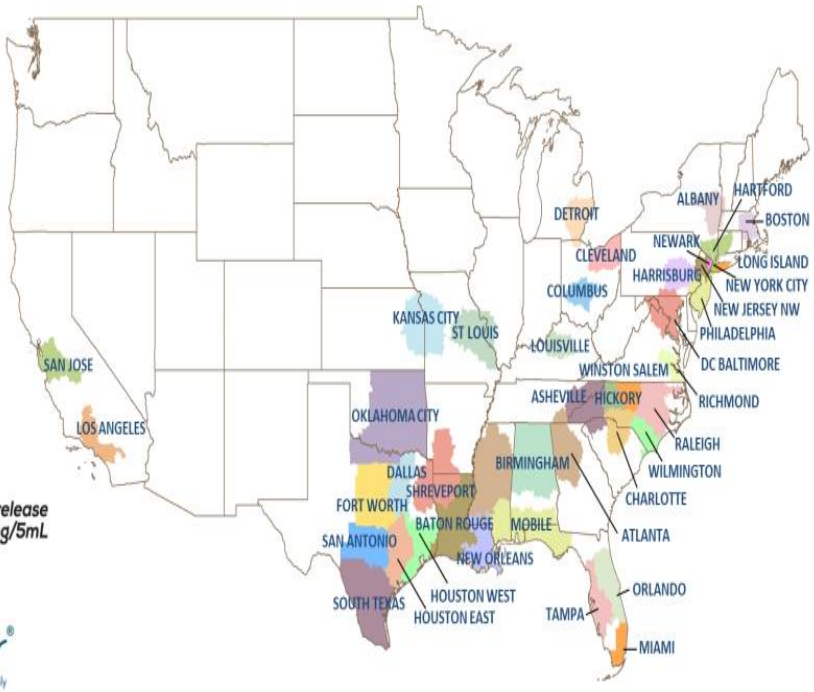
CEFACLOR For Oral Suspension, USP 125 mg/5 mL • 250 mg/5 mL • 375 mg/5 mL

Tri-Vi-Flor™

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

ulesfia® (benzyl alcohol) Lotion 5%

Oflexichamber® Anti-static Valved Collapsible Holding Chamber Rx Only




**Fully-integrated** commercial team with revenues reinvested into operations and R&D

**Capability-Building:** Sales, Operations, Regulatory, Marketing and Training

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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 May be Used in Up To 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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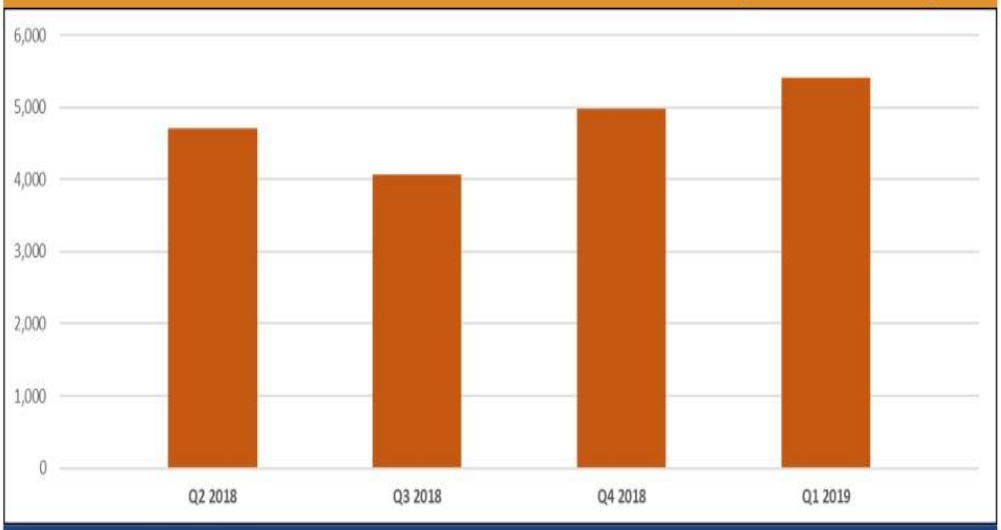
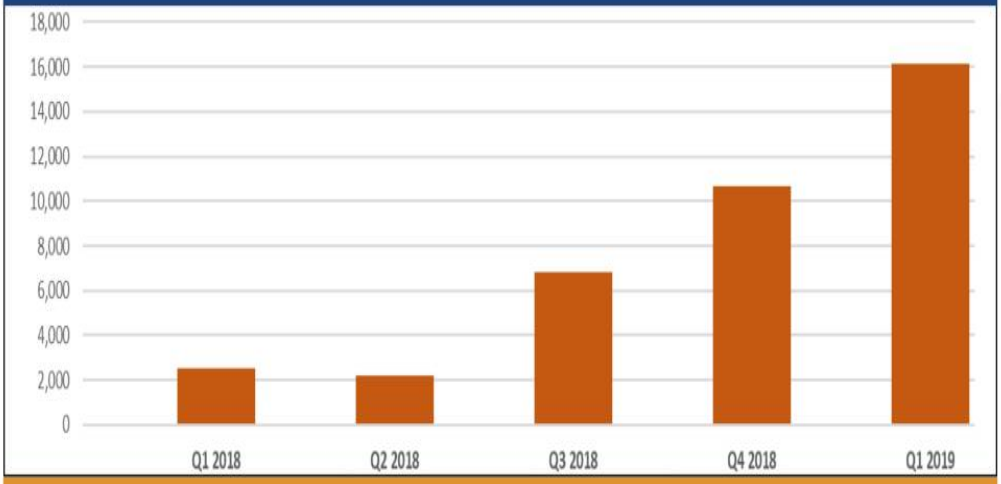
# Financials

## Net Product Sales Last 4 QTR Trend ($ Millions)




## FY19 Net Sales Guidance = $20 to $22 Million




## Cash Trend Analysis ($ Millions)

# 2019 Growth Plans

## 1 Advance Pipeline

CERC-801

CERC-802

CERC-803

CERC-301

CERC-406

CERC-913

CERC-611

## 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

Out-license / Partner indications and or geographies



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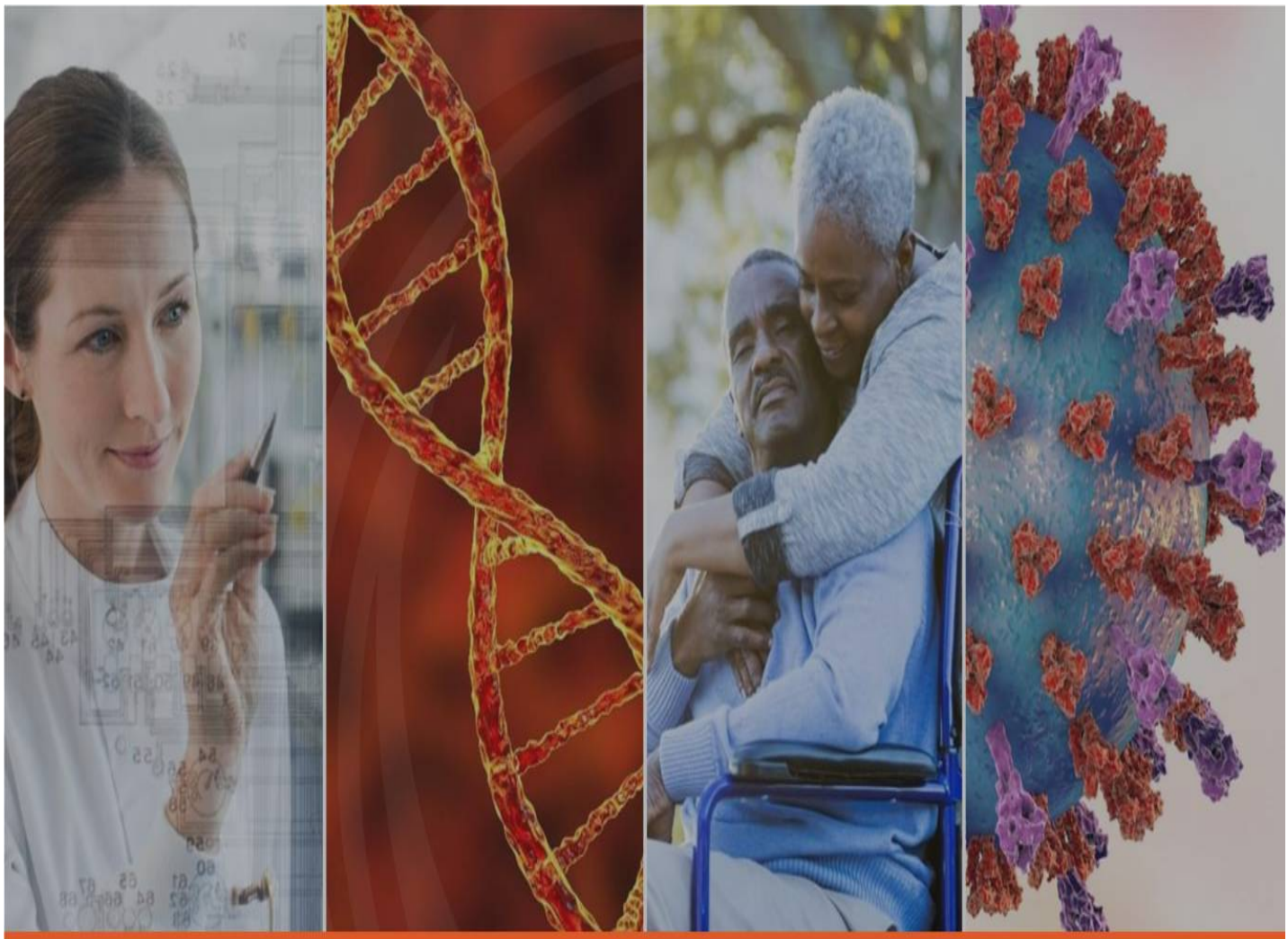

# Driven by Science

# Inspired by Hope

NASDAQ:CERC

www.cerecor.com

CERECOR