## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### **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 6, 2017

#### CAPNIA, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-36593 (Commission File No.) 77-0523891 (IRS Employer Identification Number)

1235 Radio Rd #110 Redwood City, CA 94065 (Address of principal executive offices)

 $(650)\,213\text{-}8444$  (Registrant's telephone number, including area code)

k 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 isions:
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))

#### Item 7.01. Regulation FD Disclosure

Attached as Exhibit 99.1 to this Current Report on Form 8-K is an investor presentation that Capnia, Inc. (the "Company") may use in presentations to investors from time to time.

The investor presentation attached as Exhibit 99.1 to this Report includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the slide presentation are "forward looking" rather than historical.

The information included in this Item 7.01 and in Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The Company undertakes no duty or obligation to update or revise information included in this Report or any of the Exhibits.

#### Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit is being filed as part of this Report.

Exhibit	
Number	Description

99.1 Presentation materials to be provided at JPMorgan Chase & Co.'s investor presentations

#### **SIGNATURES**

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.

Date: January 9, 2016

CAPNIA, INC.

By: /s/ David O'Toole David O'Toole Chief Financial Officer





# Corporate Presentation

January 2017

NASDAQ: CAPN

www.capnia.com

#### **Certain Notices and Disclaimers**

#### Forward-Looking Statements

This presentation contains forward-looking statements that are subject to many risks and uncertainties. Forward looking statements appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned product development and clinical trials; the timing of, and our ability to make, regulatory filings and obtain and maintain regulatory approvals for our product candidates; our intellectual property position; the degree of clinical utility of our products, particularly in specific patient populations; our ability to develop commercial functions; expectations regarding product launch and revenue; our results of operations, cash needs, and spending of the proceeds from this offering; financial condition, liquidity, prospects, growth and strategies; the industry in which we operate; and the trends that may affect the industry or us.

We may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation.

You should also read carefully the factors described in the "Risk Factors" section and other parts of our Annual Report on Form 10-K, available at <a href="https://www.sec.gov">www.sec.gov</a>, in order to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this presentation will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation or to reflect the occurrence of unanticipated events.



### **Highlights**

Capnia and Essentialis to Merge

New Lead Asset DCCF Well-Financed Through Key Milestones

Strong Leadership Longer-Term
Pipeline
Opportunities

## Creating a rare disease therapeutics company

Initial focus on PWS, a high unmet need indication with no approved treatments

#### Compelling product profile

Addresses hallmark symptoms of PWS, including hyperphagia

Phase 2/3 ready

Established, decades-long safety profile

Strong IP

## Financing concurrent with planned merger

Adequate to advance DCCR through top-line data

## Highly experienced management team

Expertise in drug development for rare and orphan diseases

#### Multiple downstream orphan indications

Hypothalamic obesity, Smith-Magenis syndrome



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## Post Merger Leadership Team

- Anish Bhatnagar, M.D. Chief Executive Officer
- David O'Toole Chief Financial Officer
- Neil Cowen, Ph.D.¹
  Senior VP of Drug Development
- Kristen Yen, M.S.VP of Clinical Operations
- Patricia Hirano, M.P.H. Regulatory Affairs





















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## Prader-Willi Syndrome (PWS)

 Complex genetic neurobehavioral/metabolic disorder due to the loss or lack of expression of a set of genes on

chromosome 15

Afflicts about 1:15,000-1:25,000 individua

- Elevated mortality rates
- Highest unmet needs
  - hyperphagia
  - aggressive behaviors
  - body composition
- PWS families have low QOL normal siblings show high rates of PTSD "Addressing these behavioral needs will be life-changing for PWS families"
  - Dr. Jennifer Miller, University of Florida







## Diazoxide – Long History of Safe Use DCCR – Extensive Pre-Clinical and Clinical Data

- Diazoxide I.V., Oral Capsule, and Oral Suspension
  - K<sub>ATP</sub> channel agonist approved in 1976
  - Previously used as IV treatment for malignant hypertension
  - BID/TID oral suspension for the treatment of hypoglycemia due to hyperinsulinism in infants, children and adults - remains global standard of care
- Diazoxide Choline Controlled-Release (DCCR)
   Tablet
  - QD tablet formulation of choline salt of diazoxide
  - Characterized in 5 Phase I and 3 Phase II studies in obese, dyslipidemic and PWS subjects
  - More than 210 treated subjects
- Protected by multiple issued patents, including
   Composition of matter

Diazoxide Choline

## **Potential DCCR Modes of Action**

Target	Action	Outcome	
Hypothalamus	Restores insulin and leptin sensitivity to POMC and NPY/AgRP neurons normalizing their regulation	Blunts central starvation signal	
Adipocytes	Down-regulates de-novo fatty acid biosynthesis and upregulates $\beta$ -oxidation of fat	Reduces fat mass	
CNS	In the context of low GABA and low GABA receptor numbers, amplifies GABA signaling	Reduces aggressive and impulsive behaviors	
Muscle	Limits excess atrophy and improves impaired mitochondrial function and energetic	Reduces hypotonia and increases muscle mass	



### PC025 Pilot Study in PWS

 Randomized, Withdrawal, Single Center Trial of DCCR in overweight or obese, genetically-confirmed PWS patients between 10 and 22 years

Double-Blind, Placebo-Controlled, Open-label Randomized Withdrawal Phase Screening **Open Label Treatment Phase** extension N=13 N=11 N=5 4 weeks 10 weeks 4 weeks 6 months Patients escalated from Continue on last DCCR dose or 1.5 mg/kg to 4.2 mg/kg placebo equivalent

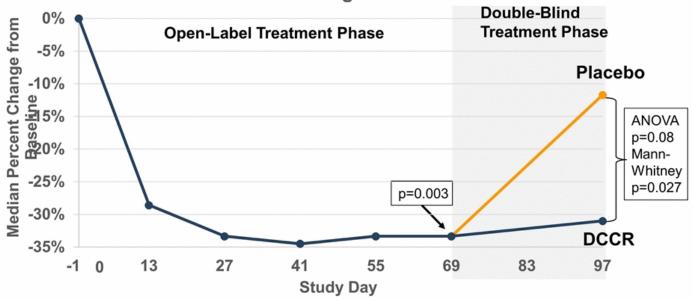
The safety and efficacy results from the study were reviewed with a panel of PWS experts



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#### DCCR: Significant Hyperphagia Response

**Median Percent Change from Baseline** 



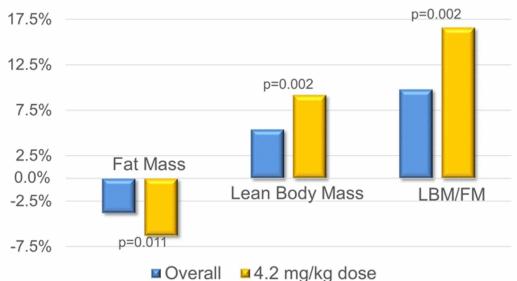
Hyperphagia was measured using a modified Dykens hyperphagia questionnaire, which assesses a range of PWS-specific food-related behaviors

Presented by Essentialis at the Annual Meeting of the Foundation for Prader-Willi Research on October 29, 2016



### **DCCR Impacts Fat/Lean Body Mass**





"The impact on fat mass and lean body mass are huge, especially in the context of improvements in hyperphagia"

- Dr. Jennifer Miller, University of Florida

Presented by Essentialis at the Annual Meeting of the Foundation for Prader-Willi Research on October

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#### **DCCR Reduces Aggressive Behaviors**

- Based on the Behavioral Assessment Questionnaire from the Prader-Willi Syndrome Natural History Study
- DCCR improved a range of behaviors that are characteristic of PWS
  - Throwing objects
  - Foul language
  - Destructive behavior

"From a family standpoint, the behavioral changes are huge. Aggression takes kids out of the home."

- Dr. Theresa Strong, FPWR

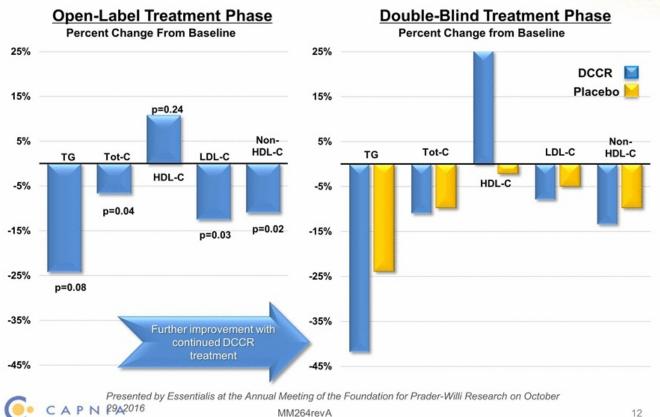
"These behavioral changes can be life-changing for the family"

- Dr. Jennifer Miller, University of Florida



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### **DCCR Impacts CV Risk Factors**



## Diazoxide – Long History of Safe Use DCCR – Extensive Pre-Clinical and Clinical Data

- The safety profile of Proglycem in chronic use is well-known
- In the development of DCCR, there have been no new safety findings
- The doses of DCCR that will continue in development are at the low end or below the labeled range for Proglycem
- More than 120,000 patient years of chronic use

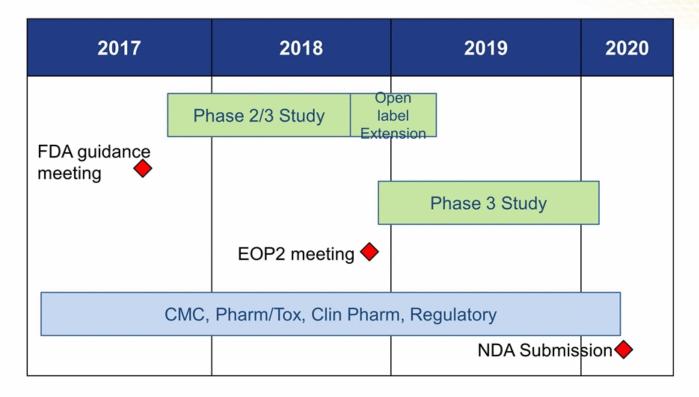
"The medication's safety profile is well known. It's a benign medication"

- Dr. Jennifer Miller, University of Florida



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### **DCCR Estimated Development Timeline**





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#### **Extensive IP Protection**

- Issued/Granted Patents
  - US: 3; EU: 3; JP: 1;
  - Also in China, Canada and Australia
  - Several pending applications
  - Expire in 2026 to 2028
  - Covers composition of matter, formulations, combinations, method of use and method of manufacture

- Protection in PWS
  - In addition to the protection of the product, our filings cover method of use of any K<sub>ATP</sub> channel activator, diazoxide and DCCR in PWS
  - New filing based on data from PC025 could extend protection to 2035



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## **Pipeline – Multiple Orphan Opportunities**

Product	Indication	US Patient Population Estimate	Timing to NDA		
DCCR	DCCR Prader-Willi Syndrome 12,500 - 21,000		2020		
Upside opportunities for DCCR					
DCCR	Hypothalamic Obesity	3,750 – 9,700	2022		
DCCR	Smith-Magenis Syndrome	12,500 – 21,000	2022		

Orphan drug designation has been granted for PWS



## **Capnia Product Portfolio**



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# Diversified, Revenue Generating Product Portfolio



#### Serenz® Allergy Relief

Serenz is a hand-held device that is designed to provide rapid relief from the symptoms related to allergies.





#### CoSense® ETCO Monitor

The *CoSense* ETCO Monitor measures carbon monoxide levels in exhaled breath, which may be used to detect the rate of hemolysis.





#### Infant Solutions

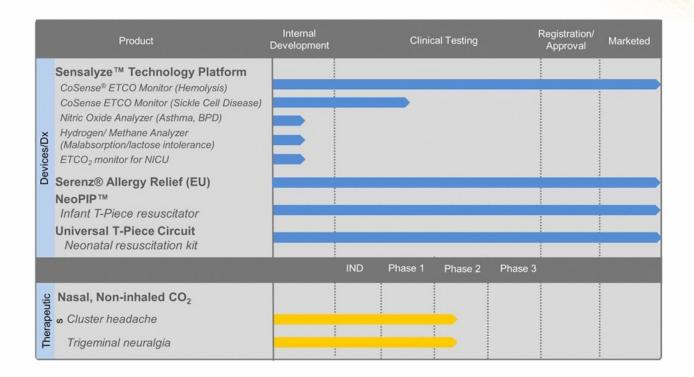
NeoForce is a portfolio of innovative pulmonary resuscitation solutions in the neonatal market.





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### **Device and Therapeutic Assets**





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#### **2017 Priorities and Milestones**

- 1Q17 Close merger transaction with Essentialis; complete concurrent \$8M financing
- Mid-2017 Complete FDA guidance meeting for DCCR
- 2H17 Initiate Phase 2/3 clinical study evaluating DCCR for the treatment of PWS
- 2017 Explore strategic alternatives for legacy marketed products and product candidates
- 2017 Secure orphan drug designation for DCCR in additional indications beyond PWS





### **Financial Highlights**

## Cash runway to value creating milestones

(millions)

,	Current <sup>1</sup>	Post-Merger <sup>2</sup>
Cash	\$5.4	\$11.0
Debt	\$0	\$0
Shares outstanding:		
Common	16.0	58.0 to 69.8
Fully Diluted	39.0	67.5 to 79.2

<sup>1.</sup> As of September 30, 2016



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Assumes an \$8 million equity financing completed at the close of the merger transaction. Additional \$2.7 million is possible.

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Thank you.

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