# 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 3, 2017**

# CAPNIA, INC.

**(Exact name of registrant as specified in its charter)**

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

**1235 Radio Road, Suite 110**
**Redwood City, CA 94065**
**(Address of principal executive offices)**

**(650) 213-8444**
**(Registrant's telephone number, including area code)**

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))

**Item 7.01 Regulation FD Disclosure**

The Essentialis presentation described under Item 8.01 below is incorporated herein by reference.

The information contained in, or incorporated into, this Item 7.01 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference to such filing.

**Item 8.01 Other Events**

On January 3, 2017, Capnia distributed a summary of Essentialis's presentation (including additional data) regarding its Phase II Clinical Study evaluating the efficacy of Diazoxide Choline Controlled-Release Tablet (DCCR), its primary product candidate at the Annual Meeting of the Foundation for Prader-Willi Research on October 29, 2016. A copy of the summary distributed by Capnia is filed as Exhibit 99.1 to this Current Report and is incorporated by reference herein.

**Participants in the Solicitation**

Capnia and its executive officers and directors may be deemed to be participants in the solicitation of proxies from its stockholders with respect to the transactions contemplated by that certain agreement and plan of merger by and between Capnia, Company E Merger Sub, Inc., Esentialis, Inc. and Neil Cowen, solely in his capacity as Stockholders Representative, dated as of December 22, 2016 (the "Merger Agreement"), pursuant to which Merger Sub will merge with and into Essentialis, and Essentialis will become a wholly-owned subsidiary of Capnia. Information regarding the persons who may, under the rules of the Securities and Exchange Commission (the "SEC"), be deemed participants in the solicitation of Capnia stockholders in connection with the proposed issuance of shares of Capnia Common Stock under the Merger and the Financing will be set forth in the proxy statement when filed with the SEC. Information regarding Capnia's executive officers and directors is included in Capnia's Proxy Statement for its 2016 Annual Meeting of Stockholders, filed with the SEC on July 18, 2016. Copies of the foregoing documents may be obtained as provided above. Additional information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of proxies in connection with the proposed issuance of shares of Capnia Common Stock under the Merger and the Financing, and a description of their direct and indirect interests in the proposed merger, which may differ from the interests of Capnia stockholders generally, will be set forth in the proxy statement when it is filed with the SEC.

**Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements within the meaning of applicable federal securities laws. Forward-looking statements contained in this Current Report on Form 8-K or in the exhibits attached hereto include, among others, statements concerning Capnia's proposed acquisition of Essentialis; and the availability of the financing that is anticipated to be consummated at or substantially contemporaneous with the closing of the merger transaction. These forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. The merger is also subject to inherent risks and uncertainties, including, among others, the following: failure of Capnia's stockholders to approve the issuance of the shares of Capnia Common Stock in the Merger and the Financing; the challenges and costs of closing, and the availability of the financing that is anticipated to be consummated at or substantially contemporaneous with the closing of the merger transaction, and other factors generally affecting the business, operations, and financial condition of Capnia, including the information contained in Capnia's Annual Report on Form 10-K for the year ended December 31, 2015, subsequent Quarterly Reports on Form 10-Q, and other reports and filings with the SEC. Additional risks, uncertainties, and other factors affecting Capnia's business will be contained in its Annual Report on Form 10-K for the year ending December 31, 2016.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Presentation of Essentialis at the Annual Meeting of the Foundation for Prader Willi Research, distributed by Capnia on January 3, 2017. |

**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.

CAPNIA, INC.

Date: January 3, 2017

By: /s/ David O'Toole
David O'Toole
Senior Vice President, Chief Financial Officer

## EXHIBIT INDEX

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**DCCR in Prader-Willi Syndrome**
**(Summary of Presentation at FPWR 2016)**

**Introduction**: Prader–Willi syndrome afflicts about 1:15,000 to 1:25,000 individuals, with the US PWS population estimated between 12,500 and 21,000. There may be as many as 350,000 PWS patients globally. Clinical features of PWS include poor feeding in infancy. Hypotonia and low lean body mass are present throughout life. Obesity typically begins around age 2 if the diet is not restricted. Ultimately, the central neurological defect of the disease causes PWS patients to sense that they are starving and signals them to significantly increase their caloric intake. This results in hyperphagia which persists for the rest of their life. Mental retardation, growth hormone deficiency, behavioral problems including aggressive, threatening and destructive behaviors, and neuroendocrine abnormalities are also characteristic of PWS. The death rate among PWS patients is 2 to 3 times that of the general population at all ages, with an average age at mortality of 29. The highest priority unmet needs in PWS as identified by parents and caregivers in a large international survey include: (1) reducing hyperphagia and improving behavior around food; (2) reducing body fat and increasing muscle mass with the potential for improved stamina and activity; and (3) reducing the temper outburst frequency and severity.

Diazoxide Choline Controlled-Release Tablet (DCCR) is a once-a-day tablet of the choline salt of diazoxide. Prior to being tested in PWS, DCCR was evaluated in 7 clinical trials in subjects with obesity and hypertriglyceridemia. Its mechanism of action in PWS is attributable to the effects of agonizing the KATP channel in multiple tissues.

**Study Design and Patient Population:** Clinical trial PC025 was a Phase II study evaluating the safety and preliminary efficacy of DCCR in patients with PWS. The trial utilized a randomized withdrawal design, was conducted at the University of California, Irvine and enrolled 13 adolescent and adult, male and female, overweight and obese genetically confirmed PWS patients. Subjects enrolled in the study were dose escalated on DCCR and then treated with a stable dose through 10 weeks of open-label treatment. Subjects then entered a four week double-blind, placebo-controlled phase where they were randomized either to remain on the DCCR dose they finished the open label-treatment phase at or its placebo equivalent, in which case they were withdrawn from the drug. A subset of subjects completed an additional six months of treatment with DCCR.

Hyperphagia, as is typical for studies in PWS, was evaluated using a questionnaire posed to the parent or caregiver using a recently developed version of the Dykens questionnaire. Body composition was evaluated using DEXA, which was run at the beginning and end of the open-label phase. Behaviors were assessed at the beginning and end of the open-label phase using a questionnaire developed for the PWS Natural History Study, evaluating 23 behaviors grouped into 4 categories. Other endpoints were measured by standard means.

**Statistical Methods**: Endpoints measured during the open-label phase were analyzed by paired t-test. Endpoints measured during the double-blind phase or over the course of both open-label and double-blind phases were analyzed parametrically by ANOVA, non-parametrically by the Mann-Whitney U test, and by arm using paired t-tests. Changes in frequency of subjects displaying categories of behavior were analyzed by Chi-square test.

**Patient Population Baseline Characteristics**: The majority of subjects were male (61.5%), deletion sub-types (93.3%). The average age of enrolled subjects was 16 years, and ranged from 11.6 to 21.6 years. There were 10 adolescents and 3 adults enrolled in the study. The average BMI was 38.1, with 3 subjects being overweight and the remainder obese based on BMI. The average percent body fat of enrolled subjects was 51.7% ranging from 36.4% to 60.7%. Baseline hyperphagia score averaged 16.3 ranging from 3 to 32. Seven of the enrolled subjects were White Hispanic or Latino; two were Asian and the remaining 4 subjects were non-Hispanic or Latino White. Six subjects were concomitantly treated with growth hormone while 7 were not.

**Results**: Hyperphagia was reduced by 32% at 10 weeks (p=0.003), the improvement persisting in those treated with DCCR in the double blind phase through more than 3 months of treatment and regressing towards baseline in those switched to placebo (p=0.027, Mann Whitney U and p=0.08, ANOVA). At the highest dose in the study, hyperphagia was reduced more than 42%.

DCCR treatment for 10 weeks also resulted in highly significant and clinically relevant impacts on body fat (-3.8%, p=0.011), lean body mass (5.4%, p=0.001), and the lean body mass/fat mass ratio (9.8%, p=0.002). These improvements were dose dependent. At the highest dose, subjects lost 6.3% of body fat, showed a 9.2% increase in lean body mass, and a 16.6% increase in lean body mass/fat mass ratio (all $p \leq 0.01$). The effects on body composition were independent of and therefore additive to growth hormone. Lipid changes at 10 weeks included triglycerides (-24.2%, p=0.08), total cholesterol (-6.7%, p=0.04), LDL-C (-12.5%, p=0.02), and non-HDL-C (-11%, p=0.01).

When present at baseline, aggressive, threatening and destructive behaviors were reduced by 73% after 10 weeks of treatment with the frequency of subjects displaying this category of behavior dropping from 70% at baseline to 20% at the end of 10 weeks of treatment (p=0.0006).

DCCR was well-tolerated with most adverse events being mild to moderate and resolving while treatment continued. The most common AEs (>20% or 3 patients) were headache, otitis media and upper respiratory infection and represented common medical complications of PWS or known side effects of diazoxide/DCCR. Two patients withdrew from the study during the open label phase, one due to a transition from home care to institutional care and another due to hyperglycemia. There were no new or unexpected safety findings in this study.

**Conclusion**

DCCR provided broad-ranging therapeutic benefit to PWS patients. It addresses the highest priority unmet needs in the disease (hyperphagia, body fat, lean body mass and aggressive behaviors) while improving cardiovascular risk factors.

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The foregoing information regarding Essentialis's Phase II Clinical Study evaluating the efficacy of Diazoxide Choline Controlled-Release Tablet (DCCR), was presented by Essentialis at the Annual Meeting of the Foundation for Prader-Willi Research on October 29, 2016, and has not been independently verified or reviewed by Capnia. Capnia is providing a summary of this presentation (including additional data) solely for informational purposes regarding the business of Capnia and Essentialis following the consummation of the transactions contemplated by the agreement and plan of merger by and among Capnia, Essentialis, Merger Sub (as defined therein), and the Stockholders Representative (as defined therein).

**About Capnia**

Capnia is a leading provider and developer of innovative healthcare products to be used for the screening, detection and treatment of medical conditions. Capnia's flagship products are based on its proprietary technologies, which utilize precision metering of gas flow. Capnia currently markets Serenz® Allergy Relief in the UK. The CoSense® ETCO Monitor measures ETCO, which can be used to detect hemolysis and the Infant Solutions product line, including innovative pulmonary resuscitation devices for neonates and infants, are marketed globally. Capnia is also clinically evaluating its nasal, non-inhaled $CO_2$ technology to treat trigeminally-mediated pain conditions such as cluster headache and trigeminal neuralgia. For more information, please visit www.capnia.com.

**About Essentialis**

Essentialis is a privately-held clinical-stage pharmaceutical company focused on the development of breakthrough medicines for the treatment of rare metabolic diseases where there is increased mortality and risk of cardiovascular and endocrine complications.

**Capnia's Forward-Looking Statements**

The foregoing presentation contains forward-looking statements that are subject to many risks and uncertainties. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ability to complete the merger and initiate the Phase II/III trial in the second half of 2017.

We may 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 herein, 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. As a result of these factors, we cannot assure you that the forward-looking statements in this presentation will prove to be accurate. Additional factors that could materially affect actual results can be found in Capnia's Form 10-Q filed with the Securities and Exchange Commission on November 14, 2016, including under the caption titled "Risk Factors." Capnia expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.