SCYNEXIS INC Form 8-K August 11, 2015

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): August 11, 2015

SCYNEXIS, Inc.

(Exact name of registrant as specified in its charter)

Delaware 001-36365 56-2181648
(State or other jurisdiction of incorporation) File Number) General Gene

3501-C Tricenter Boulevard Durham, North Carolina 27713 (Address of principal executive offices, including zip code)

(919) 544-8600

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

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 Disclosures.

SCYNEXIS, Inc. (the "Company") will present at and conduct investor meetings during the Canaccord Genuity \$5 Annual Growth Conference on August 12–13, 2015 in Boston, Massachusetts. In connection with the presentation and meetings, the Company intends to discuss the slide presentation attached as Exhibit 99.1 (the "Corporate Presentation") to this current report on Form 8-K (the "Current Report"). The Company's current development strategy and outlook for its lead product candidate, SCY-078, is described in the Corporate Presentation. Recent updates to our SCY-078 development strategy and outlook include the following:

We are currently conducting a multicenter Phase 2 study with primary endpoints of safety, tolerability, and pharmacokinetics of the oral formulation of SCY-078 as step-down treatment in patients initially treated with echinocandin therapy for invasive Candida infections. The enrollment into the study continues but has been slower than anticipated. New investigational sites have been opened, the study protocol has been amended to facilitate enrollment and further amendments are being considered. We are planning to open additional investigational sites in the US, we intend to open sites outside of the US and we are evaluating subsequent amendments to the protocol. These measures are expected to increase enrollment into the study. In addition, as we collect data on the enrolled patients, we will continue to assess the actual number of patients required to achieve the study objectives. We expect to complete the study and to report top line data in the first half of 2016.

We are currently developing an IV formulation of SCY-078. Following a pre-submission meeting with the FDA, we are planning to submit the data package, including data from our IND-enabling studies, and to start the first Phase 1 study with the IV formulation in the fourth quarter of 2015.

We are also planning to investigate the potential clinical utility of SCY-078 in other areas of unmet medical need such as genital infections caused by Candida spp. (vulvovaginal candidiasis, VVC). VVC is a highly prevalent condition with limited therapeutic options for infections caused by azole-resistant Candida spp. We are planning to commence a Phase 2 study evaluating the safety and efficacy of orally administered SCY-078 in this indication during the fourth quarter of 2015. Top line results are expected in the first half of 2016. The data from this study is also expected to provide a confirmation of the potential therapeutic effect of orally administered SCY-078 in a clinical condition caused by Candida spp. and, along with the other clinical and nonclinical data from ongoing and planned activities, will contribute to the package of information that will support subsequent phases of development.

In accordance with General Instruction B.2. of Form 8-K, the information contained in Item 7.01 in this report (including the Corporate Presentation) 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, nor shall the Corporate Presentation be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing. This Current Report will not be deemed a determination or an admission as to the materiality of any information in the Corporate Presentation that is required to be disclosed by Regulation FD.

Item 9.01 Financial Statements and Exhibits

Exhibit No. Description

99.1 Corporate Presentation

### **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.

SCYNEXIS, Inc.

Dated: August 11, 2015 By: /s/ Jonathan Sears Woodall

Jonathan Sears Woodall

Interim Chief Financial Officer

## EXHIBIT INDEX

Exhibit No. Description

99.1 Corporate Presentation