

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
(State or other jurisdiction
of incorporation)

001-36365
(Commission
File Number)

56-2181648
(IRS Employer
Identification No.)

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))
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Item 7.01 Regulation FD Disclosures.

SCYNEXIS, Inc. (the “Company”) will present at and conduct investor meetings during the Canaccord Genuity 35th 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

<u>Exhibit No.</u>	<u>Description</u>
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

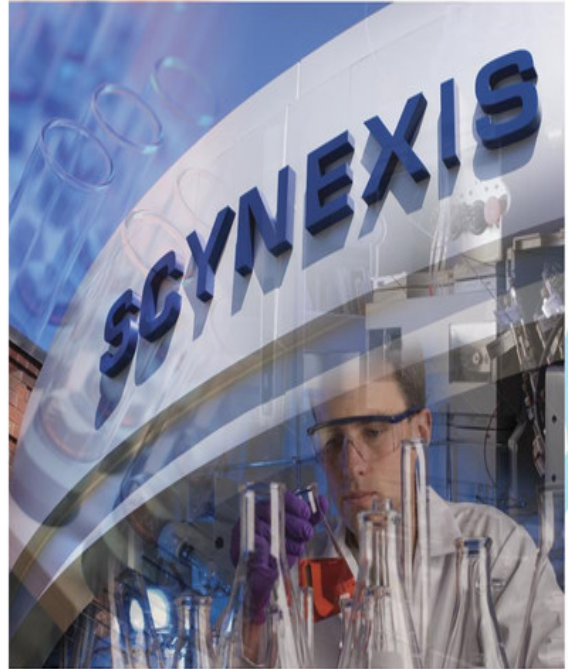
<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation



SCYNEXIS, Inc.

Speed and Innovation in Anti-Infectives

**Canaccord Conference
Boston, August 12-13, 2015**



Forward-looking Statements



Certain statements regarding SCYNEXIS, Inc. (the "Company") made in this presentation may constitute forward-looking statements, including, but not limited to, statements regarding our business strategies and goals, plans and prospects, market size, adoption rate, potential revenue, clinical validity and utility, growth opportunities, future products and product pipeline. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risk and uncertainties include but are not limited to our ability to successfully develop SCY-078, including an IV formulation of SCY-078; our expectations regarding QIDP designation; our ability to obtain FDA approval for SCY-078; the expected costs of studies and when they will begin and our reliance on third parties to conduct our clinical studies. Forward-looking statements may be identified by the use of the words "anticipates," "expects," "intends," "plans," "could," "should," "would," "may," "will," "believes," "estimates," "potential," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, risks and uncertainties discussed in the company's most recent reports filed with the Securities and Exchange Commission ("SEC") including the Company's quarterly report on Form 10-Q filed with the SEC on May 15, 2015 and other risks and uncertainties detailed from time to time in the Company's filings with the SEC, which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. The Company undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this presentation, or to reflect actual outcomes.

Experienced Management Team



- **Management team with significant experience in drug development**

- Successful track record in many therapeutic areas including antifungals and other anti-infectives products

Marco Taglietti, MD
Chief Executive Officer

- CEO effective April 2015
- Former CMO of Forest Labs and President of the Forest Research Institute
- Former Head of R&D at Stiefel Labs and of Anti-Infectives at Schering-Plough

David Angulo, MD
Chief Medical Officer

- CMO effective June 2015
- Previously with Brickell Biotech, Stiefel and Schering-Plough
- Infectious Disease Specialist with more than 10 products approved

Jon Woodall
Chief Financial Officer

- Interim CFO from CMF Associates, LLC
- Previously CFO at M&F Bancorp, Community Health and Gilero
- Certified Public Accountant, Former Big-4 partner

- **Some recent changes to the Board of Directors**

- **Guy Macdonald**, Tetrphase President and CEO, appointed Chairman of the Board
- **Steve Gilman**, former Chief Scientific Officer at Cubist, appointed Member of Board

Investment Highlights



- **Significant unmet medical needs in a \$3.6B+ antifungal market**
- **Favorable regulatory environment with clear path to registration**
 - Multiple FDA QIDP product approvals in the past year, including Dalvance (Durata), Sivextro (Cubist), Orbactiv (Medicines), Zerbaxa (Cubist), Cresemba (Astellas) and Avycaz (Actavis)
- **SCY-078 is a Phase 2 novel, innovative antifungal with QIDP and Fast Track status**
 - Mechanism of action validated by echinocandins
 - IV and oral formulations for flexibility of administration like azoles
 - *in vitro / in vivo* activity against *Candida* and *Aspergillus*, including drug resistant strains
 - Well-tolerated oral administration in Phase 1 studies in ~100 healthy subjects

SCY-078	DISCOVERY	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3
SCY-078 (Oral)	[Progress bar spanning Discovery, Pre-clinical, and Phase 1]				
SCY-078 (IV)	[Progress bar spanning Discovery and Pre-clinical]				

- **Candidiasis and Aspergillosis are serious and life threatening fungal infections with growing resistance**
- **Invasive Candidiasis remains a serious clinical problem**
 - 4th most common cause of hospital-acquired blood infection in US
 - Mortality rate of 27 to 40% despite treatment
 - Identified by CDC as an antimicrobial resistance threat
 - Increasing prevalence of azole resistant *Candida spp.* and Multi Drug Resistant (MDR) species, like *C. glabrata*
 - Limited therapeutic options for MDR *Candida* infections
 - Drug resistant *Candida* infections associated with higher mortality, hospital cost and longer length of stay
 - Treatment guidelines changing as result of resistance
- **Invasive Aspergillosis**
 - 2nd most common invasive hospital-acquired fungal infection in US
 - Mortality approaches 50% despite treatment

Limited number of antifungal options -- Only three classes of antifungals --



POLYENES

Ambisome (\$450M¹), amphotericin B

- ↑ Effective vs a broad range of fungi
- ↓ Significant toxicity (renal, cardiac, infusion)
- ↓ Limited activity against *C. glabrata*
- ↓ Only IV administration

AZOLES

voriconazole (\$754M²), fluconazole, posaconazole, isavuconazole

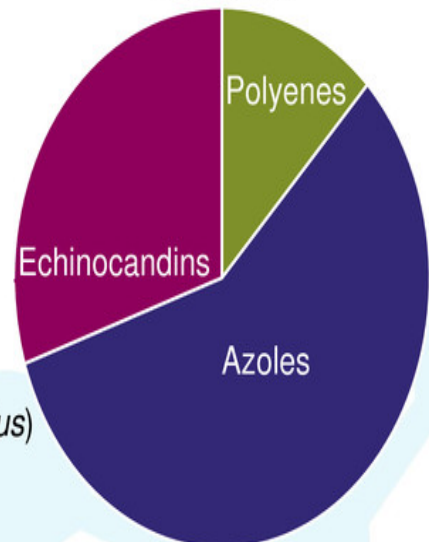
- ↑ Good efficacy with flexible administration (both IV and oral)
- ↓ Rising resistance to azoles (*C. glabrata*, *C. krusei*, *Aspergillus*)
- ↓ Liver toxicity and drug interactions

ECHINOCANDINS

casprofungin (\$619M²), micafungin, anidulafungin

- ↑ Effective (drug of choice in invasive candidiasis)
- ↑ Good tolerability profile
- ↓ Some *Candida* strains are showing resistance
- ↓ Only IV administration

\$3.6B+ Sales²
Invasive Fungal
Infections



1) Lipid amphotericin B sales in 2012

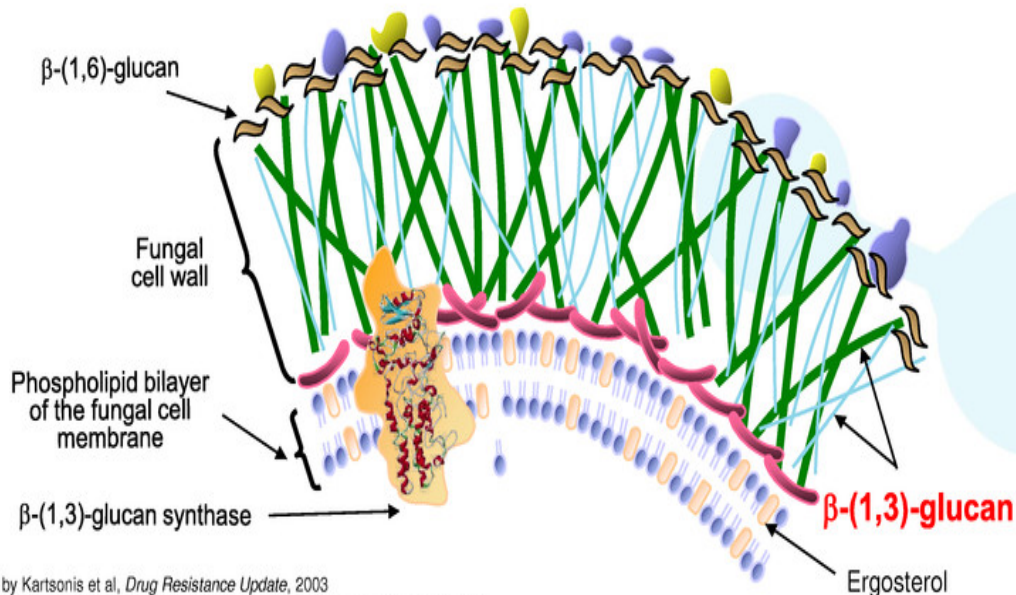
2) Approximate, as measured by sales in 2011

SCY-078: Validated Mechanism of Action



- **SCY-078 targets synthesis of β -(1,3)-glucan in fungal cell wall**

- Mechanism validated by echinocandins
- Disruption of fungal cell wall with fungicidal effect in *Candida*
- No β -(1,3)-glucan in human cells, therefore no direct human cell toxicity
- No cross-resistance with azoles because of different mechanism



Adapted by Kartsonis et al, *Drug Resistance Update*, 2003
Anderson Freitas Pinheiro et al. *International Journal of Quantum Chemistry*, 2012

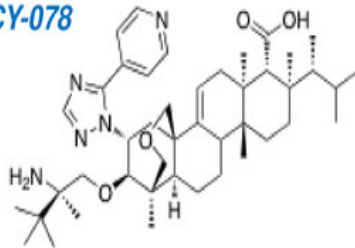
SCY-078: Unique Product Attributes



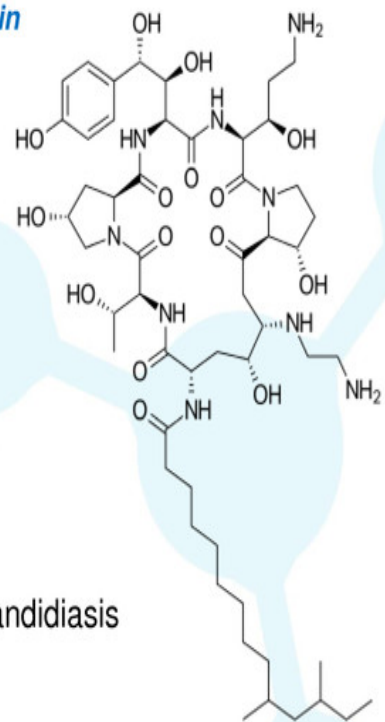
- **SCY-078 is a first-in-class enfumafungin antifungal in clinical development**

- New chemical class from natural compound
- First non-azole with IV and oral formulations in development

SCY-078



Caspofungin



- Composition-of-matter IP with long patent life
- Activity against *Candida* and *Aspergillus* spp.
 - Including azole- and echinocandin-resistant strains
- Favorable safety and tolerability profile
- Manageable drug-drug interactions
- QIDP and Fast-Track designation by FDA for invasive candidiasis and invasive aspergillosis with the oral formulation

SCY-078: Microbiology profile



- Broad activity against *Candida* species *

<i>Candida</i> spp.	MIC ₉₀ µg/mL (MIC range)	Fluconazole	Caspofungin	SCY-078
	<i>C. albicans</i> (29)	≥128 (0.06 - ≥128)	2 (0.015 - 8)	1 (0.06 - 2)
	<i>C. glabrata</i> (29)	≥128 (2 - ≥128)	16 (0.03 - 16)	2 (0.5 - 2)

- Activity against multi drug resistant *Candida* strains

Multi Drug Resistant * <i>Candida</i> spp.	MIC (range)	Fluconazole	Caspofungin	SCY-078
	<i>C. albicans</i> (4)	16 - ≥128	2 - 8	0.12 - 1
	<i>C. glabrata</i> (4)	64 - ≥128	2 - 16	1

- Ongoing microbiology studies to further characterize activity of SCY-078 in recent clinical isolates and resistant strains

* Isolates were selected for testing to represent both wild-type and antifungal-resistant strains of each species.
Pfaller M. A and Col., *J. Antimicrobial Agents and Chemotherapy*, 2013; 68(4); 858-863.

- **Development risks in anti-infectives are lower than in other areas**
 - The pathogen is an external target with predictive *in vitro* and *in vivo* models
 - Well established PK/PD models
 - Significantly de-risked development projects once in the clinical stage

- **Favorable current regulatory environment simplifies and accelerates development with significant financial incentives**
 - GAIN Act (July 2012)
 - New pending regulations (DISARM, ADAPT, 21st Century Cures)
 - Multiple FDA approvals of QIDP products over the past year

- **Impact of Current and Pending Legislation**
 - Increased awareness of urgent need for new antifungals to fight resistance
 - Additional market exclusivity
 - Possibility for faster development pathway
 - Pending legislation may provide pricing power in resistant patient populations

SCY-078: Well-tolerated in Phase 1



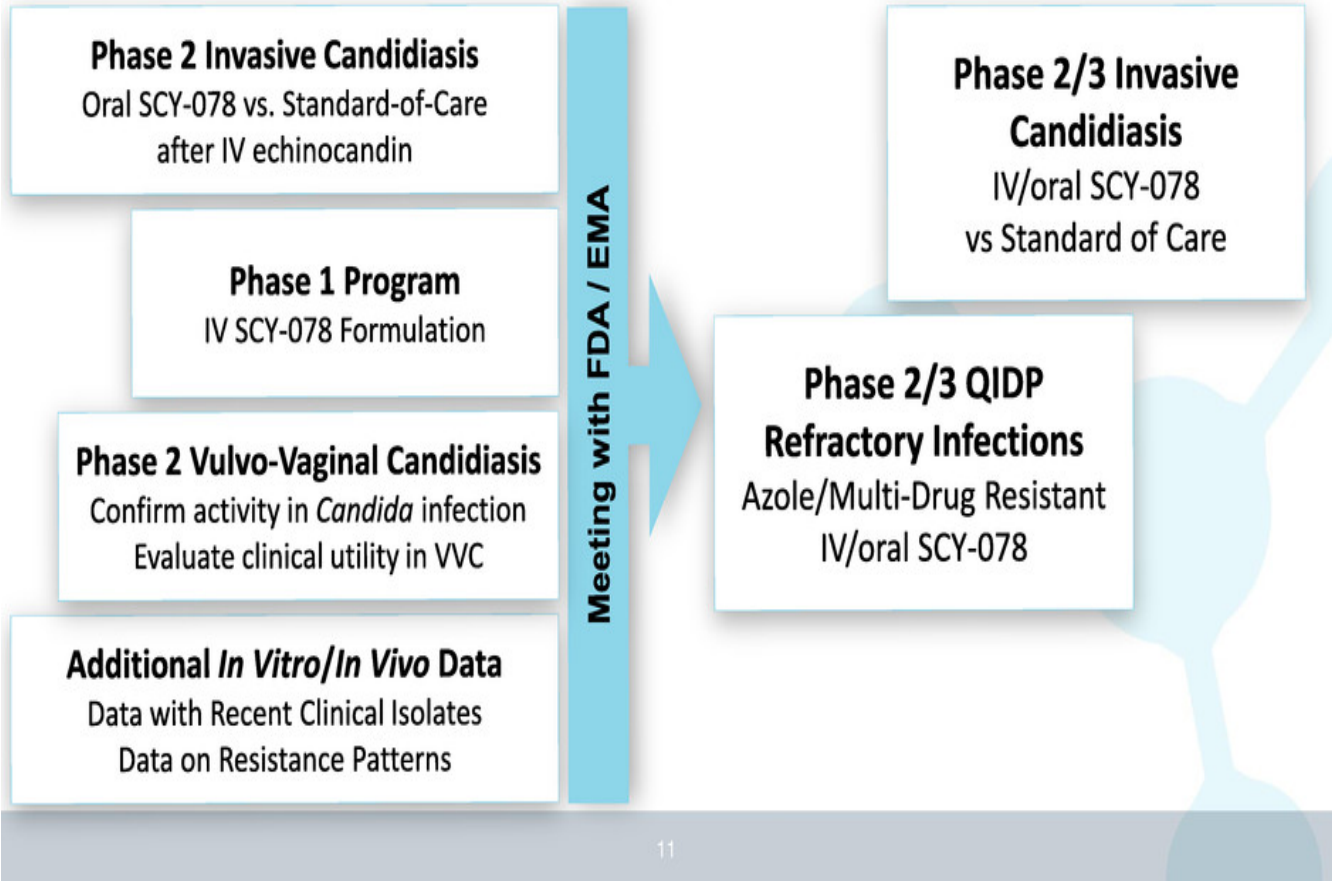
- **SCY-078 evaluated in seven Phase 1 studies in ~100 healthy subjects**
 - Well characterized oral PK
 - Half-life supports once daily dosing
 - Predicted human efficacious oral dose of ~500-750mg daily based on murine disseminated candidiasis PK/PD studies
- **Favorable safety and tolerability profile**
 - Safe and well-tolerated at single oral doses up to 1600mg and multiple doses of 800mg/day for up to 28 days
 - Most common adverse events were gastrointestinal (nausea, diarrhea)
 - Majority of adverse events were mild to moderate and did not lead to discontinuation of therapy
- **Metabolized primarily by glucuronidation and oxidative mechanisms involving CYP-3A4**

SCY-078: Clinical Plan in Invasive Candidiasis



- **Clear path to registration in Invasive Candidiasis**

- Targeting both primary and salvage treatment in refractory infections
- Phase 2 Study in VVC to strengthen evidence of clinical efficacy against *Candida*

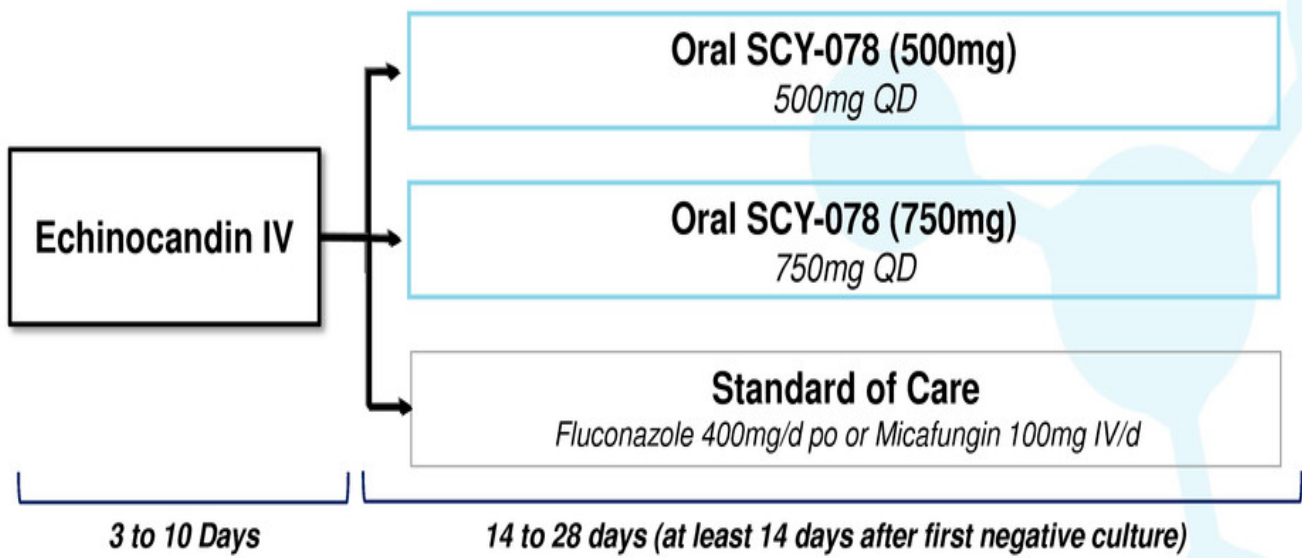


SCY-078: Ongoing Phase 2 in IC, Study Design



● Oral step-down following IV Echinocandin

- Randomized, open-label study to assess two different doses of SCY-078 versus standard of care as an oral step-down treatment following an IV echinocandin
- Primary Endpoint: Safety, tolerability and PK/PD of two oral doses of SCY-078
- Secondary and exploratory Endpoints: Efficacy at end of treatment with antifungals, relapse rate and activity against *C. glabrata* and *C. krusei*
- First patient enrolled in March 2015
- New sites being considered and amendments being implemented to facilitate enrollment



SCY-078: Planned Phase 2 in VVC



Randomized, evaluator-blinded to assess two different dose regimens of Oral SCY-078 versus standard of care (Fluconazole) in subjects with moderate to severe VVC

- Two dose-regimens of oral SCY-078 (5 days or 3 days) compared to standard dose-regimen of Fluconazole.
- Assessment
 - Day 24 (Primary Test of Cure efficacy, TOC)
 - Week 8 and Week 16 (Secondary efficacy endpoint)
- Primary Endpoint: Safety and Efficacy (therapeutic outcome) at TOC
- Secondary Endpoints: Relapse rates, clinical & microbiological outcomes - Month 4
- Approximately 30 patients per arm to be enrolled and followed for up to 4 months
- Initiation planned for 4Q 2015 with topline results (Day 24 Test of Cure) expected by first half of 2016

SCY-078: Target Indications



- **Invasive Candidiasis is the first target indication**

- Primary and salvage therapy in Invasive Candidiasis

- **SCY-078 Positioning in Invasive Candidiasis**

- Treatment for refractory, multi-drug resistant pathogens
- Alternative IV treatment to echinocandins allowing step-down option



- Step-down options following IV dosing of any echinocandin



- **Additional potential future indications**

- Invasive Aspergillosis
- Prophylaxis of Invasive Fungal Infections
- Vulvo-Vaginal Candidiasis, including recurrent VVC

SCYNEXIS Milestones



Achieved

- ✓ Jan-2014 QIDP Status for Oral
- ✓ May-2014 IPO Completed
- ✓ Oct-2014 Waterstone Deal (SCY-635)
- ✓ Dec-2014 IV Formulation Selected
- ✓ Dec-2014 Fast Track for Oral
- ✓ Mar-2015 IV IND GLP Tox Started
- ✓ Mar-2015 First Patient in Phase 2 Oral
- ✓ Apr-2015 Follow-on Public Offering
- ✓ Jul-2015 Sale of the Service Business

Projected

- 2H-2015
 - ❑ Start Oral Phase 2 study in VVC
 - ❑ Start IV Phase 1 Program
- 1H-2016
 - ❑ QIDP Status for IV
 - ❑ Top Line Phase 2 Oral Invasive Candidiasis
 - ❑ Complete IV Phase 1 Program
 - ❑ Top Line Phase 2 VVC
 - ❑ Additional *In Vitro* / *In Vivo* Data
- 2H-2016
 - ❑ FDA / EMA Meetings
 - ❑ Fast Track for IV
 - ❑ Initiate QIDP Refractory Trial

Financial Highlights



- **Initial Public Offering May 2014**
 - \$62mm raised (gross proceeds)
 - Repaid \$15mm debt
 - Top-tier Life Sciences Investors
- **\$41mm Follow-On Offering Completed April 2015** (gross proceeds)
- **\$57mm Cash as of June 30, 2015**
 - Funds company into H1-2017
 - SCY-078 development
 - Ongoing Phase 2 study in IC
 - IV formulation Phase 1 studies
 - Phase 2 study in VVC
 - Pre-clinical *in vitro* / *in vivo* susceptibility and resistance data
 - CMC for the registration programs
 - Commencement of the registration clinical studies

Committed to the development and commercialization of novel anti-infectives to address significant unmet therapeutic needs

- **SCY-078: Innovative QIDP / Fast Track product in Phase 2**
 - Unique combination of attributes of safety, efficacy and flexibility of administration
 - Activity against resistant fungal strains, including multi-drug resistant pathogens
 - Well tolerated orally in ~100 subjects
 - IV and oral administration
- **A clear path to registration**
 - Favorable regulatory environment
 - QIDP and Fast Track status granted for the oral formulation
 - Significant financial legislative incentives
- **An experienced team to execute the plan**

