# 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): January 9, 2015**

# SCYNEXIS, Inc.

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

| **Delaware** | **001-36365** | **56-2181648** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (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))

**Item 7.01 Regulation FD Disclosures.**

SCYNEXIS, Inc. (the “Company”) will conduct investor meetings during week of January 12, 2015 in San Francisco, California. In connection with the 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").

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 8.01 Other Events.**

On January 9, 2015, the Company issued a press release announcing the receipt of Fast Track designation for oral SCY-078 from the U.S. Food and Drug Administration. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.2 to this Current Report, which is incorporated by reference.

**Item 9.01 Financial Statements and Exhibits**

| Exhibit No. | Description |
|---|---|
| 99.1 | Corporate Presentation |
| 99.2 | Press Release issued on January 9, 2015 |

**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: January 9, 2015

By: /s/ Charles F. Osborne, Jr.
Charles F. Osborne, Jr.
Chief Financial Officer

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
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# SCYNEXIS, Inc.

January 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") 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.

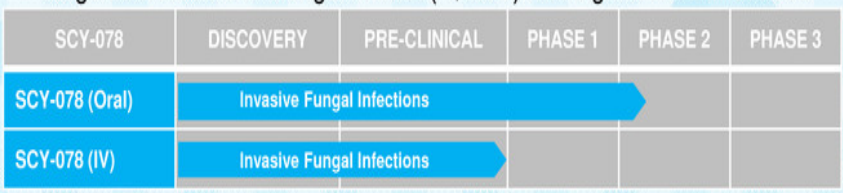
# Investment Highlights

Pharmaceutical company committed to the discovery, development and commercialization of novel anti-infectives to address significant unmet therapeutic needs

## Lead Asset: SCY-078

**Novel oral and IV antifungal compound in Phase II development**

- Effective *in vitro* and *in vivo* against clinically relevant *Candida* and *Aspergillus spp.*, including drug-resistant strains
- Well-tolerated in Phase 1 studies in ~100 healthy subjects
- Favorable regulatory environment: QIDP and Fast Track designations received from FDA
- Large addressable antifungal market (~$3.6B) with significant unmet need




## Non-Core Assets

**Revenue generating with additional R&D platforms provide partnership opportunities**

- Cyclophilin inhibitor platform SCY-635 licensed to Waterstone Pharmaceutical (HK)
- Established animal drug discovery services platform partnered with Sanofi-Merial and Dechra, Ltd

# Invasive Fungal Infections Pose a Serious Clinical Problem

- **Invasive candidiasis**
  - Most common invasive fungal infection and 4th most common cause of hospital acquired blood stream infection in US
  - Mortality 25 to 40% despite treatment
  - Identified by CDC as an antimicrobial resistance threat in 2013
    - Increasing prevalence of *Candida spp.* with high level of resistance to azoles and increasing prevalence of Multi Drug Resistant species (*C. glabrata*)
    - Limited therapeutic options for azole and echinocandin resistant *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**
  - Second most common invasive fungal infection
  - Mortality approaches 90% in the most severely immunocompromised

*Due to high mortality associated with a delay in treatment, ~2/3 of systemic antifungal use occurs before a diagnosis is confirmed*

# Limitations of Current Antifungal Treatments

| Antifungal Class | Approved Antifungal Drug | IV/Oral | Mkt Size |
|---|---|---|---|
| I. Azoles | voriconazole, fluconazole, posaconazole | IV/Oral | $2.1bn[1] |

Voriconazole Sales[2]: $747mm

- Increasing Resistance in *C. glabrata, C. krusei, Aspergillus spp*
- Newer agents have broader spectrum but significant drug interactions and adverse events

| | | | |
|---|---|---|---|
| II. Echinocandins | caspofungin, micafungin, anidulafungin | IV only | $1.1bn[1] |

Caspofungin Sales[2]: $669mm

MOA: Blocks fungal cell wall biosynthesis (β-1,3 glucan synthesis) *(Cidal)*

- Resistance emerging in *Candida spp.*
- Treatment of choice for IC - favorable safety profile and few drug interactions

| | | | |
|---|---|---|---|
| III. Polyenes | AmBisome® | IV only | $500mm[2] |

MOA: Binds to ergosterol and disrupts fungal cell integrity *(Cidal)*

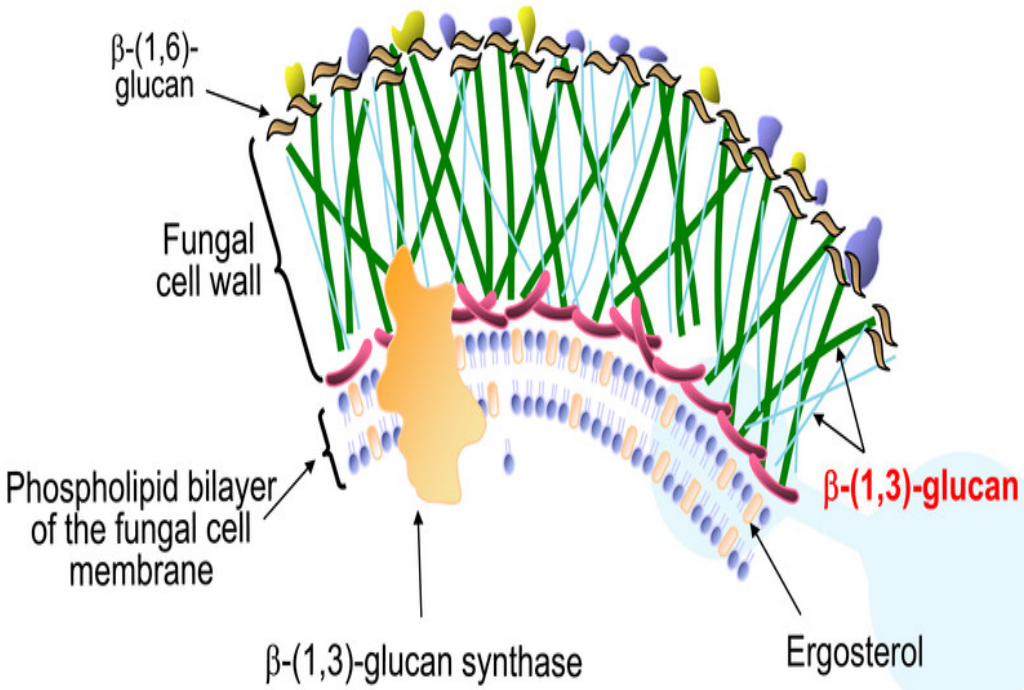
- Use is limited by toxicity (renal, infusion related events, electrolyte depletion, cardiac)
- Limited *C. glabrata* activity

***In contrast to antibacterials, there are a limited number of antifungal classes***

*1) Approximate, as measured by sales in 2011 2) As measured by sales in 2012*

# SCY-078 Mechanism of Action

SCY-078 targets synthesis of β-(1,3)-glucan in fungal cell wall;
Target validated by echinocandins




Kartsonis et al, *Drug Resistance Update*, 2003

# SCY-078 Key Product Attributes

- SCY-078 is a first-in-class enfumafungin antifungal
  - New chemical class issued from natural compound
    - Strong IP with long patent life
  - First non-azole with IV and oral formulations
    - IV formulation IND enabling studies underway, FIM 2H-15
    - Oral formulation entering Phase 2 1H-2015
  - Activity against *Candida* and *Aspergillus spp.*, including azole- and echinocandin-resistant strains
  - Favorable safety and tolerability profile
  - Manageable drug-drug interactions

# SCY-078 Significantly De-risked vs. Phase 2 Assets in Other Therapeutic Areas

- Development in anti-infectives is unusual
  - The target (a microbe) can be isolated
  - The drug works on the microbe, not the patient
  - Studies in a test tube (MICs) and in animal models reliably predict efficacy in man
- Unlike most other drugs…
  - Antibiotic blood levels,
  - The minimum inhibitory concentration (MIC) of the drug for the bug, and
  - Response have a predictable relationship: with rare exception the concentrations of drug in a mouse that are effective are also effective in man
- Still need other data, primarily safety, but PK/PD significantly de-risks concerns about efficacy failures

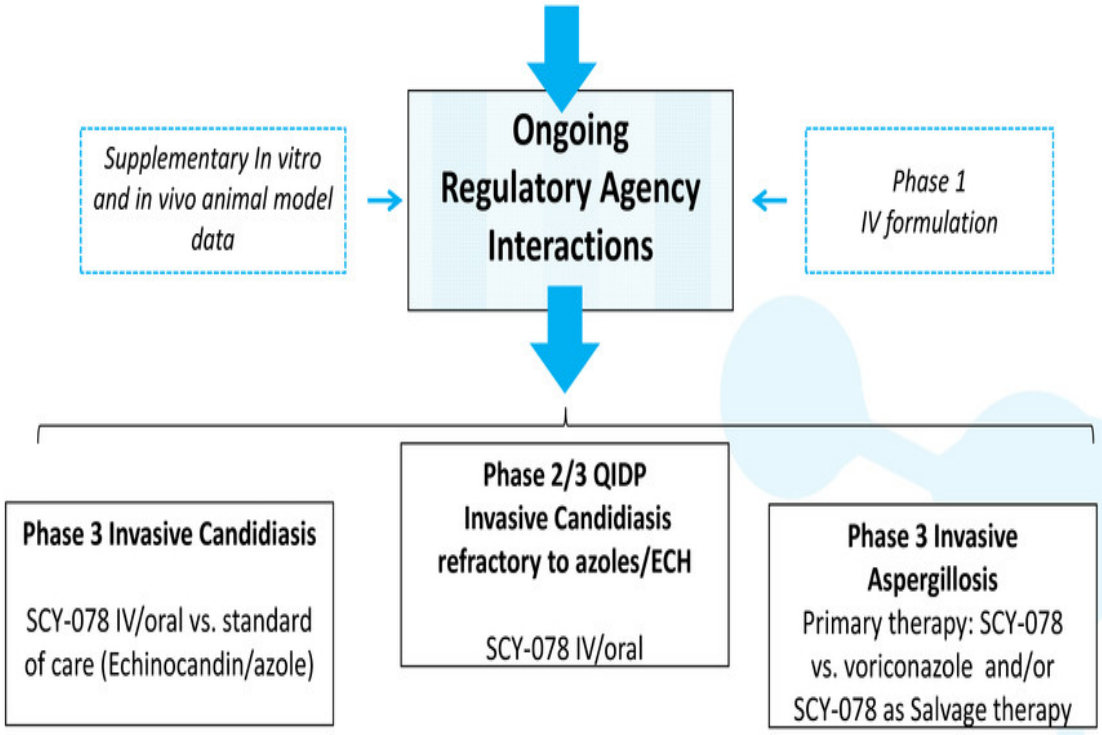
# SCY-078: Well-tolerated in Phase 1

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

# Favorable Regulatory Environment

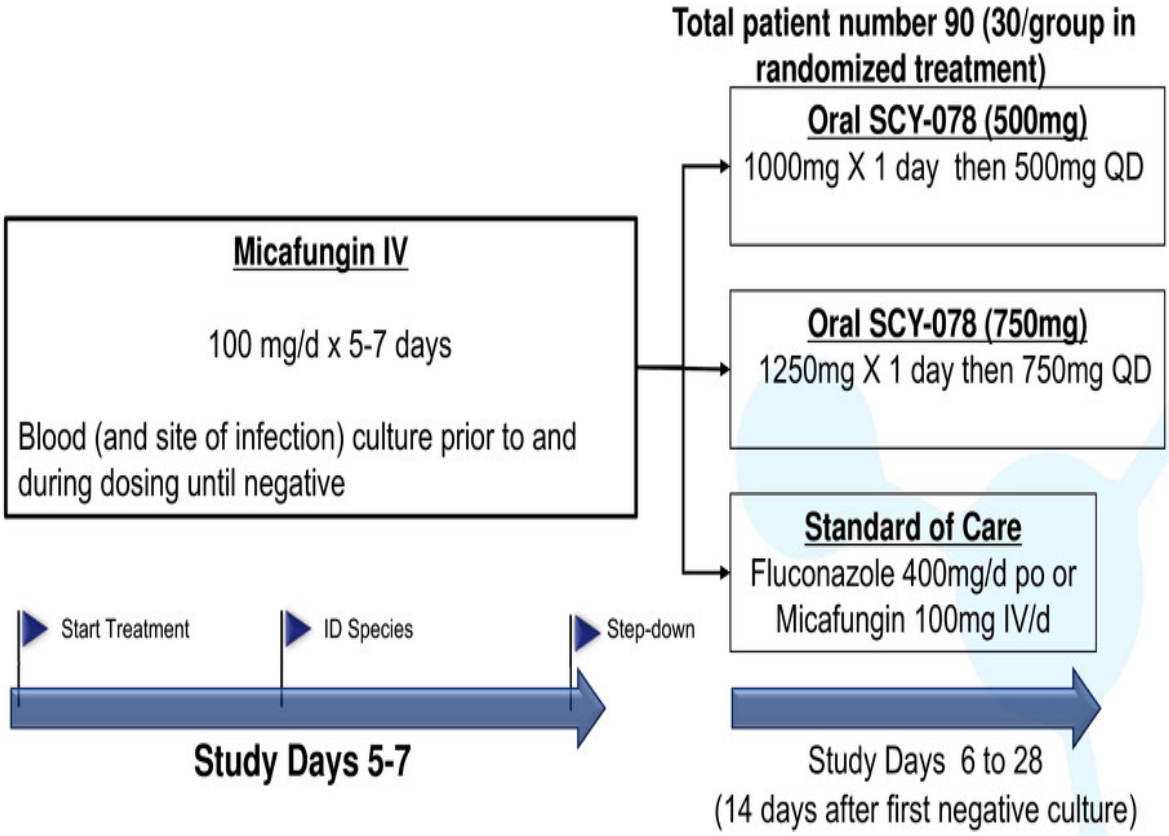
- GAIN Act
  - SCY-078 oral formulation granted QIDP designation by FDA for invasive candidiasis and invasive aspergillosis
- Fast Track
  - SCY-078 oral formulation granted Fast Track designation by FDA for invasive candidiasis and invasive aspergillosis
- DISARM Act (Introduced)
  - Allowing value based pricing for antimicrobial products
- ADAPT Act (Pending)
  - Allow FDA to promptly approve drugs for targeted and limited patient populations
- Impact of Current and Pending Legislation
  - Increased awareness of urgent need for new antifungals
  - Additional market exclusivity
  - Possibility for faster development pathway
  - Potential for pricing power in resistant patient populations

# SCY-078 Clinical Development Program



# Phase 2: Invasive Candidiasis
# Oral Step-down from IV Micafungin

**A Phase 2, Open-Label, Randomized, Active-Controlled, Safety, Tolerability and Efficacy Study of Oral SCY-078 Therapy Following Intravenous Micafungin in Hospitalized Subjects with Documented Invasive Candidiasis.**



# Phase 2 Invasive Candidiasis Study Objectives

| Primary Objectives | PK, Safety |
|---|---|

- Determine the dose of SCY-078 that achieves target AUC of 15 µM·hr in ≥ 80% of patients (day 1 and end of therapy)
  - Based on Phase 1 data and modeling and simulation, a sample size of 30 patients would be sufficient
- Evaluate safety and tolerability in patients receiving dosing regimens predicted to be efficacious

| Secondary Objective | Efficacy |
|---|---|

- Regimen of micafungin followed by oral SCY-078 in the overall population
- SCY-078 in subset of patients with *C. glabrata* and *C. krusei*
- Will assess results in context of prior invasive candidiasis studies

# Invasive Candidiasis: First Indication

- Invasive candidiasis
  - Most common invasive fungal infection with high morbidity and mortality
  - Echinocandins currently preferred therapy
  - Ability to demonstrate efficacy and safety in area of unmet need due to increasing resistance
- SCY-078 potential for primary and salvage therapy and as step down from other antifungals:
  - Clinical studies to confirm efficacy and PK/PD
    - Phase 2 oral stepdown study
    - Phase 2 IV/oral SCY-078 as salvage therapy for patients with limited therapeutic options
    - Phase 3 Noninferiority study as primary therapy vs. standard of care
- Most rapid time to market, if successful, is salvage therapy

# Additional Indications

- Invasive Aspergillosis
  - Salvage therapy in patients refractory to or intolerant of approved treatment (data support indication for prophylaxis, pre-emptive therapy)
  - Option to explore first line treatment compared to voriconazole
- Prevention of *Candida* and *Aspergillus* infections in high risk patients
- Pediatrics

# Projected Milestones

- SCY-078 for invasive antifungal infections
  - First patient enrolled in oral formulation Phase 2 study for the treatment of invasive *Candida* infection 1Q--15
  - IV formulation selection and IND-enabling studies 1H-15
  - FIM IV formulation 2H-15
  - Complete Phase 2 Data 1H-16
- Monetization of non-core assets

# Financials

- Initial Public Offering May 2, 2014
  - $62mm Raised
  - Top-tier Life Sciences Investors
- Cash Balance $34mm as of September 30, 2014
  - Funds SCY-078 Development Through Q1-2016
  - Non-Core Assets Potential Source of Non-Dilutive Capital
- Share Count
  - 8.5mm Shares Outstanding
  - 9.3mm Fully Diluted

# Management Team

## Management team with significant experience in drug discovery and development

| | |
|---|---|
| **Yves Ribeill, PhD**<br>**President & CEO** | ▪ CEO and a Member of Board of Directors since 1999<br>▪ 20-year international pharmaceutical career with Aventis Pharma and Rhône-Poulenc Rorer<br>▪ Former Infectious Diseases Director |
| **Carole Sable, MD**<br>**Chief Medical Officer** | ▪ CMO since January 2014<br>▪ Former VP Infectious Disease Research and later VP Project Leadership, Neuroscience at Merck<br>▪ Developed Cancidas through approval at Merck<br>▪ Former CMO Novexel SA |
| **Chuck Osborne, Jr.**<br>**Chief Financial Officer** | ▪ CFO since November 2003<br>▪ Former CFO of Nobex Corporation and VP of Finance for International Murex Technologies<br>▪ Certified Public Accountant |

# SCYNEXIS Key Highlights

Pharmaceutical company committed to the discovery, development and commercialization of novel anti-infectives to address significant unmet therapeutic needs

**SCY-078**
**Ph II, novel, next generation antifungal addressing a large and growing unmet medical need of increasing antifungal resistance**

- Enfumafungin
  1st non-azole with both IV and oral formulation
- Broad activity against Candida and Aspergillus spp
- FDA QIDP and Fast Track Designations

Strategic partnering and monetization of non-core assets

Strong cash position through Q1-2016

Experienced and proven management team

**SCYNEXIS, Inc. Receives FDA Fast Track Designation for Oral Formulation of SCY-078 for the Treatment of Patients with Invasive Fungal Infections**

**Research Triangle Park, N.C.** (January 9, 2015) – Drug discovery and development company SCYNEXIS, Inc. (NASDAQ: SCYX) today announced that the U.S. Food & Drug Administration (FDA) has granted Fast Track designation for the oral formulation of SCY-078, the Company's novel antifungal product in development for invasive *Candidiasis*, including *Candidemia* and invasive *Aspergillosis*. SCYNEXIS is currently screening patients for a Phase 2 study of the oral formulation of SCY-078 and expects to enroll the first patient in the first quarter of 2015.

"This Fast Track designation, coupled with our prior receipt of QIDP designation, allows for an accelerated path to approval and underscores the FDA's understanding of the critical need for new and varied treatments for life-threatening invasive fungal infections," said Yves J. Ribeill, Ph.D., President and Chief Executive Officer of SCYNEXIS. "We now have multiple trial sites open and we look forward to reporting complete data in the first half of 2016."

The FDA's Fast Track Drug Development Program is a process designed to facilitate the development and expeditious review of drugs to treat serious conditions and fill an unmet medical need. This designation allows for companies to interact with the FDA review team frequently to discuss critical development issues such as study design, required safety data necessary to support approval, and structure and content of a New Drug Application. Additionally, should the FDA determine that a Fast Track product may be effective after their preliminary evaluation of clinical data submitted by a sponsor, the FDA may also consider reviewing portions of a marketing application before the sponsor submits the complete application.

**About SCY-078**

SCY-078 (formerly MK-3118) is an oral glucan synthase inhibitor being developed for the treatment of invasive fungal infections including *Candidemia* and invasive *Aspergillosis*. SCY-078 is a semi-synthetic derivative of the natural product enfumafungin—a structurally distinct class of glucan synthase inhibitors. Glucan synthase inhibitors have been very effective in treating invasive fungal infections in a hospital setting, but are currently only available in intravenous formulations. The FDA designated SCY-078 as a Qualified Infectious Disease Product (QIDP) for oral use for the indications of invasive *Candidiasis*, including *Candidemia*, and invasive *Aspergillosis*. SCYNEXIS is developing both oral and intravenous formulations of SCY-078.

**About Invasive Fungal Infections**

Invasive fungal infections (IFI) are serious, often life-threatening infections caused by a variety of fungal species. The most common invasive fungal infections stem from *Candidiasis* and *Aspergillosis*, responsible for approximately 85 percent of all invasive fungal infections in the U.S. and Europe. The incidence of invasive fungal infections has increased significantly over the past two decades, as the populations of patients at risk have continued to rise. Morbidity and mortality remain high despite the currently available antifungal agents. Because there are limited treatment

options, and they are used widely, there has been an increase in the number of infections due to drug-resistant strains.

**About SCYNEXIS**

SCYNEXIS is a pharmaceutical company committed to the discovery, development and commercialization of novel anti-infectives to address significant unmet therapeutic needs. We are developing our lead product candidate, SCY-078, as an oral and intravenous (IV) drug for the treatment of serious and life-threatening invasive fungal infections in humans. For more information, visit www.scynexis.com.

**Forward Looking Statement**

Statements contained in this press release regarding matters that are expected to occur in the future are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in SCYNEXIS's filings with the Securities and Exchange Commission, including without limitation its most recent Quarterly Report on Form 10-Q and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. SCYNEXIS undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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