

**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 9, 2018**

**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.)

**1 Evertrust Plaza, 13th Floor**  
**Jersey City, New Jersey 07302-6548**  
(Address of principal executive offices, including zip code)

**(201)-884-5485**  
(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))
-

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).  
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 7.01 Regulation FD Disclosure.**

On August 9, 2018, SCYNEXIS, Inc. made available its investor slide presentation (“Corporate Presentation”), which is attached as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

**Exhibit Index**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#"><u>Corporate Presentation</u></a>

**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 9, 2018

By: /s/ Eric Francois  
Eric Francois  
Chief Financial Officer

The logo for SCYNEXIS, with 'SCY' in purple and 'NEXIS' in orange. A small purple circle is positioned above the 'X'.A large, semi-transparent, circular microscopic image of a biological structure, possibly a fungus, with many small, rounded protrusions, serving as a background for the text.

Ibrexafungerp (formerly SCY-078)  
First Representative of a Novel Oral/IV  
Triterpenoid Antifungal Family

Corporate Presentation – Aug. 2018

*“Committed to positively impacting the lives of patients suffering from difficult-to-treat and often life-threatening infections”*

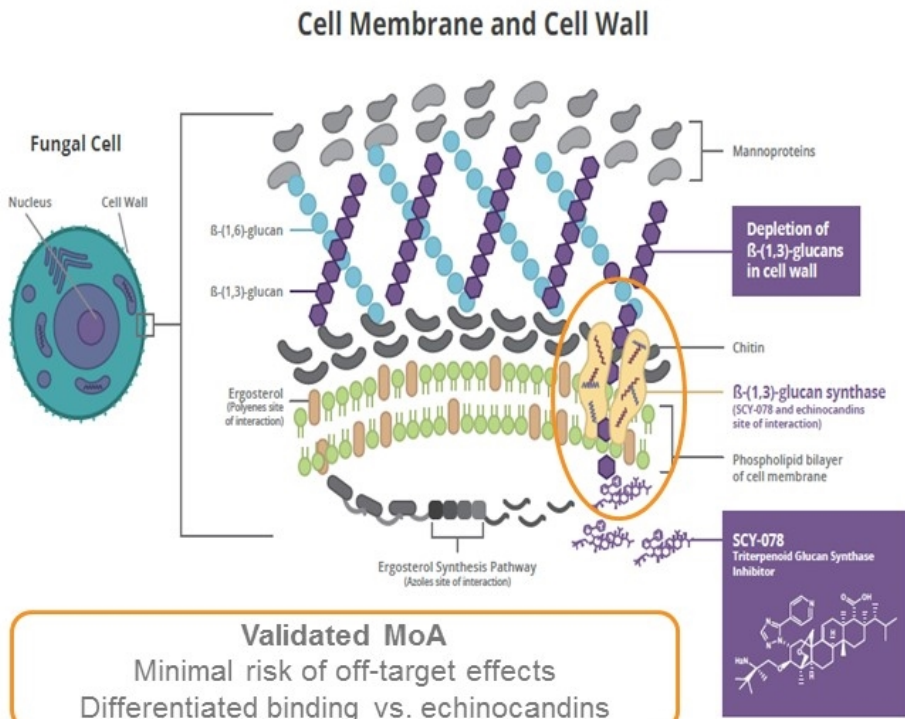
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# Forward-Looking Statements

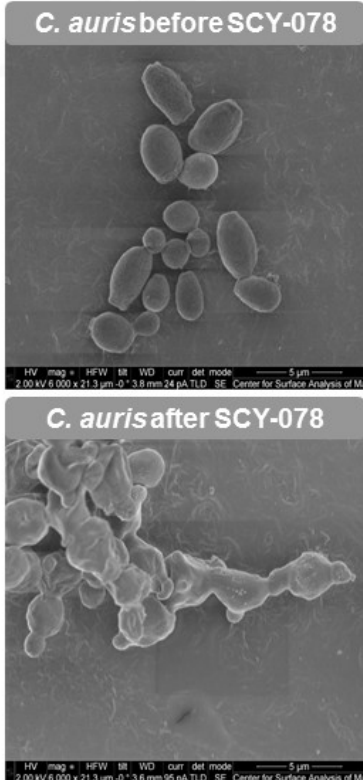
Certain statements regarding SCYNEXIS, Inc. (the “Company”) made in this presentation constitute forward-looking statements, including, but not limited to, statements regarding our business strategies and goals, plans and prospects, market size, adoption rate, potential revenue, clinical validity and 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 risks and uncertainties include, but are not limited, to: risks inherent in SCYNEXIS’s ability to successfully develop and obtain FDA approval for ibrexafungerp; the expected costs of studies and when they might begin or be concluded; and SCYNEXIS’s reliance on third parties to conduct SCYNEXIS’s 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 under the caption “Risks Factors” in the Company’s annual report on Form 10-K, 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.



# Ibrexafungerp (SCY-078) MoA: Glucan Synthase Inhibitor



**Validated MoA**  
Minimal risk of off-target effects  
Differentiated binding vs. echinocandins



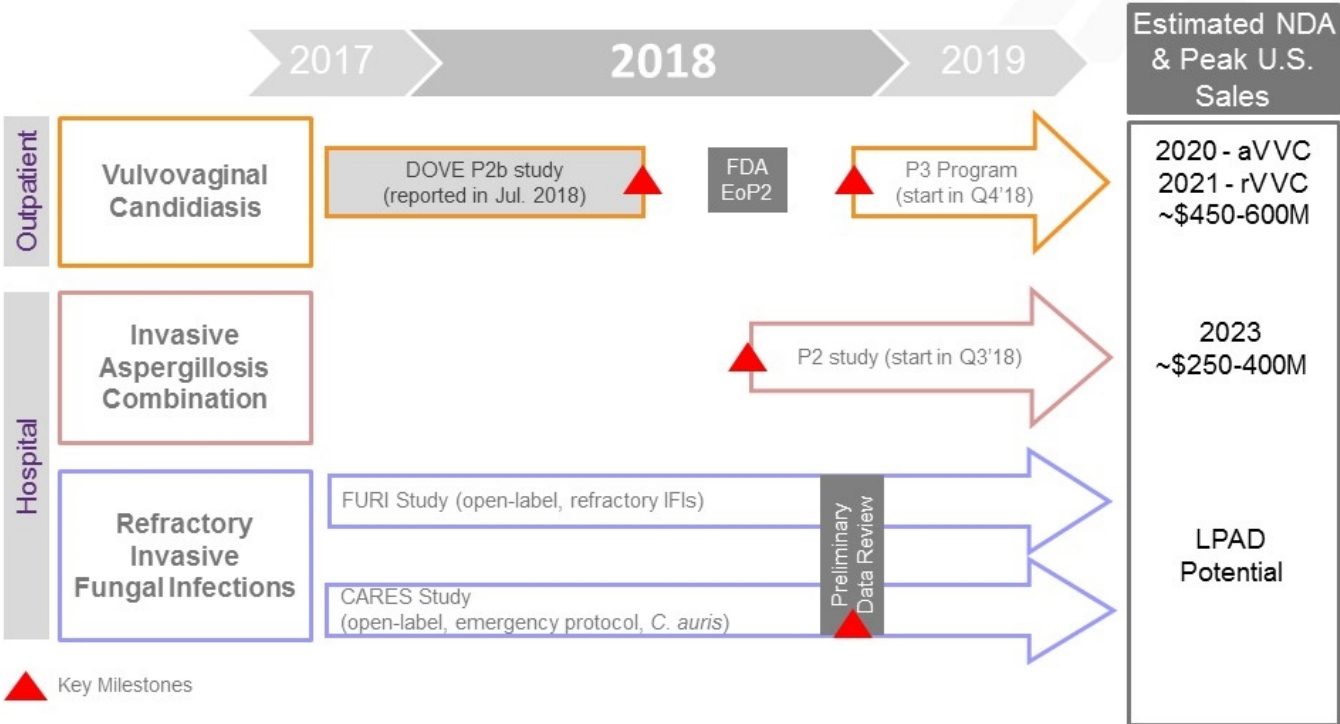


# Ibrexafungerp: Key Attributes vs. SoC Agents

	Ibrexa	Echinocandin	Azole	Polyene
Market Intro	~2021	2000s	1980s	1960s
Worldwide 2016 Sales <sup>a</sup>		~\$1B	~\$800M	~\$500M
Spectrum of Activity	Active vs. <i>Candida albicans</i>	✓	✓	✓
	Active vs. non- <i>albicans Candida</i>	✓	✓	✓
	Active vs. azole-resistant	✓	✓	✓
	Active vs. echinocandin-resistant*	✓		✓
	Active vs. <i>Aspergillus</i> spp.	✓	✓	✓
Safety	Lack of Renal, Hepatic, CNS Tox	✓	✓	
	Low Risk for DDIs	✓	✓	✓
	Flexibility of Use (Oral/IV)	✓		✓



# Ibrexafungerp Oral Development Plans



Other potential oral indications: Prophylaxis, Chronic Fungal Infections

# Ibrexafungerp IV Development Plans

## >70 subjects exposed to IV ibrexafungerp

- No systemic safety concerns (i.e., renal, hepatic, etc.)
- Local injection site reactions to address

## Liposomal formulation to improve local tolerability in pre-clinical development

- Prototype formulation showed an improved tolerability profile
- Scaled-up product displayed less favorable tolerability than prototype
- Scale-up process under investigation

## Next steps

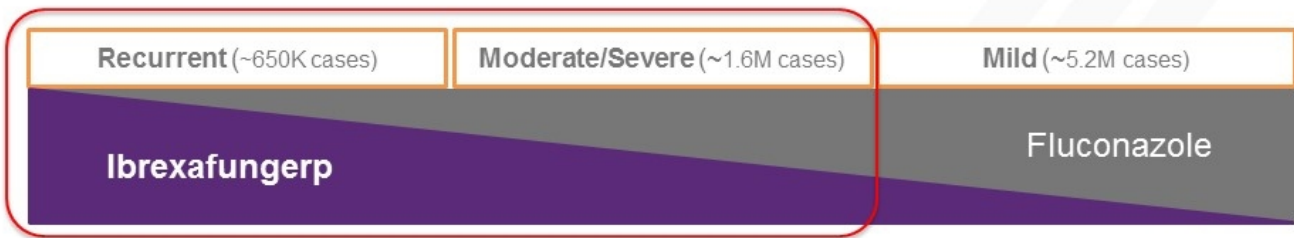
1. Develop revised scale-up process
2. Resume IND-enabling toxicology studies
3. Conduct Phase 1 study in healthy volunteers
4. Conduct clinical studies in patients
  - Invasive candidiasis, including candidemia
  - Other hospital-based indications for additional treatment flexibility

# Vulvovaginal Candidiasis (VVC)

*“Many of the unresolved clinical issues in managing women with rVVC would disappear if truly fungicidal drugs and regimens were available.”*

Dr. Jack Sobel  
Curr. Infect. Dis. Rep. 2006;8:481-486

# Ibrexafungerp Positioning in VVC



## Ibrexafungerp Key Benefits

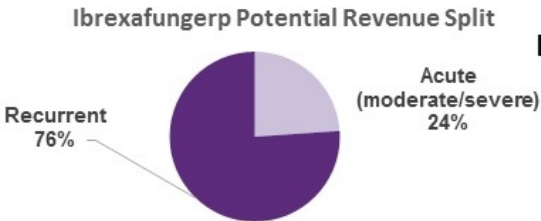
- High and sustained clinical activity
- Activity vs. resistant strains
- Fungicidal activity
- High penetration into vaginal tissue and enhanced activity in the low pH vaginal environment
- No evidence of embryo/fetal development toxicity in pre-clinical studies

## Target Patient Populations

- Recurrent cases
- Moderate-to-severe cases
- Fluconazole-resistant, intolerant and non-responders cases
- Non-*albicans Candida* infections
- Women of child-bearing age

# Ibrexafungerp U.S. Opportunity in VVC

	RECURRENT VVC	ACUTE VVC (MODERATE/SEVERE)
U.S. TARGET POPULATION	~650K	~1.6M
IBX PENETRATION RATES	~40%	~15%
IBX PRICING – PER COURSE	~\$1,350 to \$1,800	~\$450 to \$600
IBX U.S. NET SALES	~\$350-470M	~\$110-150M



**Ibrexafungerp U.S. Sales Potential ~\$450-600M**

Conservative estimates → Ibrexafungerp potential sales represent ~6% of overall fluconazole prescriptions in VVC

ROW opportunity expected to be similar to U.S. market

# Ibrexafungerp Phase 2b DOVE Study

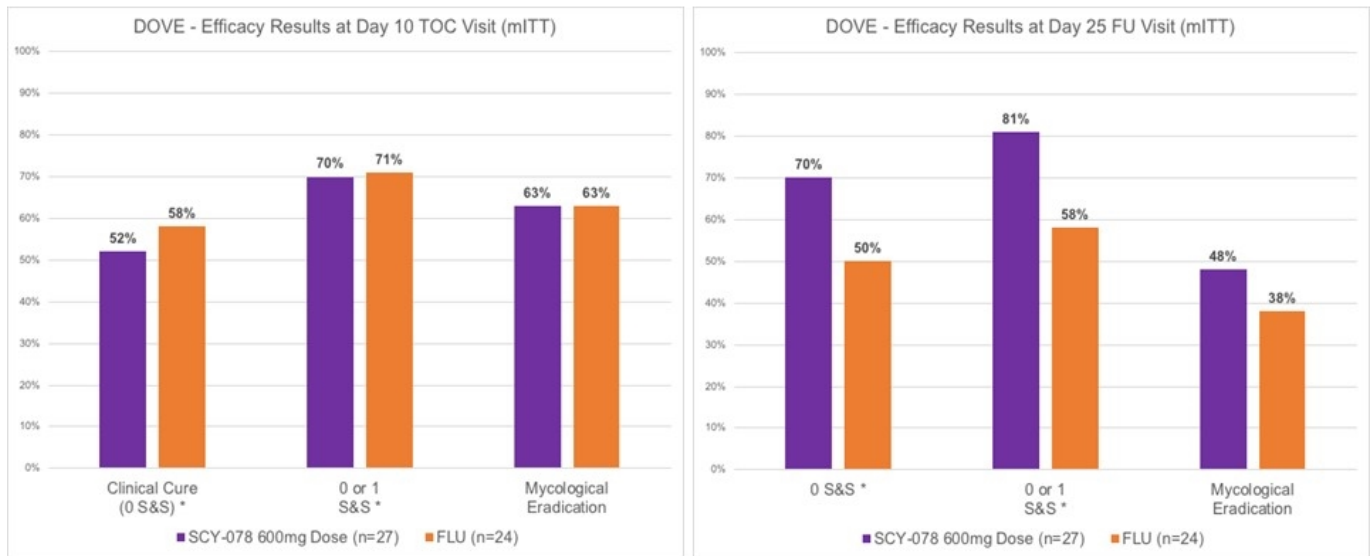
- Randomized, multi-center, double-blind, active-controlled, dose-finding study to identify optimal oral dose of ibrexafungerp for Phase 3 program
  - 186 ITT patients with moderate-to-severe acute VVC (S&S  $\geq 7$ )
  - 153 mITT patients (cultured-confirmed primary efficacy population)
- Efficacy parameters:
  - Clinical cure at Day 10 (ToC; Primary Endpoint)
    - Resolution of all signs and symptoms (Total Score = 0)
    - No further rescue antifungal treatment
  - Clinical outcome at Day 25 Follow-up visit (FU)
  - Mycological eradication at Days 10 and 25
  - Total Score of Signs & Symptoms of 0 and 1 at Days 10 and 25
  - Use of antifungal rescue therapy
  - Changes from baseline signs and symptoms

# Phase 2b DOVE Study Key Findings

- **Ibrexafungerp 600mg dose** for one day (given as 2 doses of 300mg 12 hours apart) as optimal dose
- High clinical and mycological activity with sustained clinical response over time
- Clinical data consistent with ibrexafungerp's attributes:
  - Fungicidal vs. *Candida*
  - High vaginal tissue penetration
  - Enhanced activity at the low pH characteristic of the vaginal environment
- Safe and well-tolerated
  - No serious AEs or discontinuations
  - Gastrointestinal (GI) events were mild to moderate and of short-duration
- Plan to move ibrexafungerp 600mg dose into phase 3 program



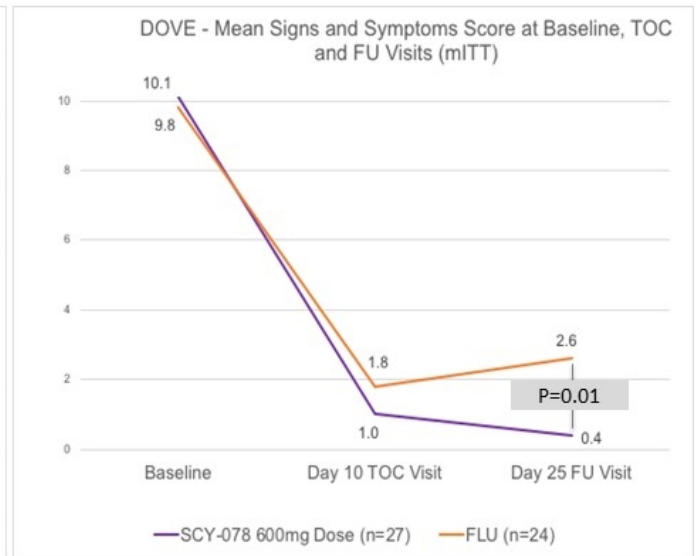
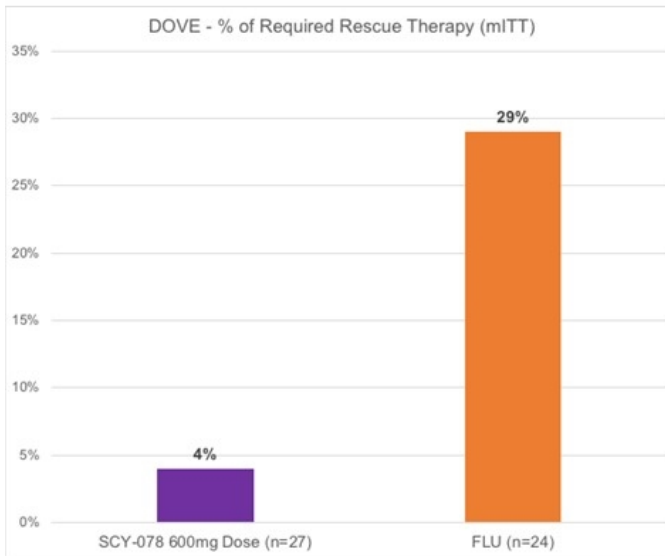
# Key Efficacy Results of P2b DOVE Study – Ibrexafungerp 600mg Dose



Results based on mITT population | \*No rescue antifungal use.

Signs and Symptoms [S&S] score defined as a composite endpoint of the subject's reported symptoms (burning, itching and irritation) and the investigator's assessed signs (swelling, redness and excoriations). Each sign and symptom can be absent, mild, moderate or severe, with a corresponding score from 0 to 3. The total composite scale goes from 0 to 18 points.

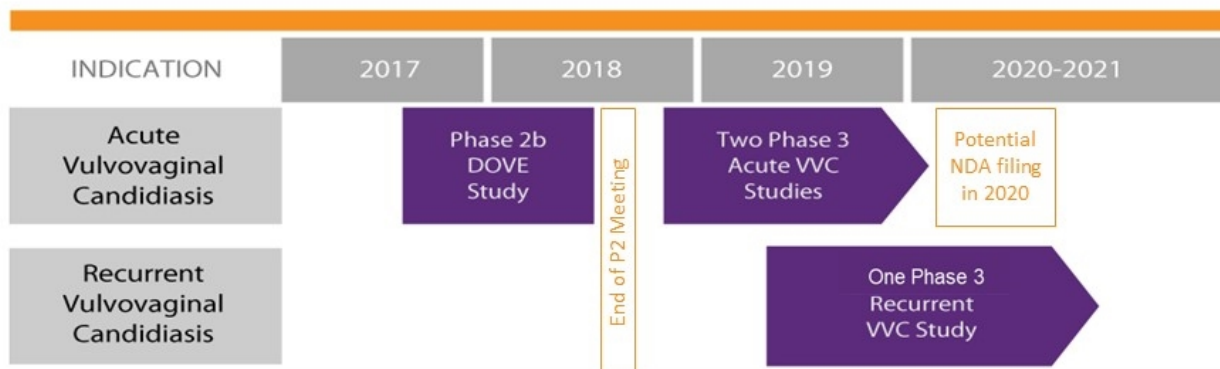
# Additional Efficacy Parameters of P2b DOVE Study – Ibrexafungerp 600mg Dose



P value based on change from baseline score mean difference between SCY-078 600mg and FLU.

Results based on mITT population.  
Mean signs and symptoms score based on 0-18 scale.

# Ibrexafungerp Path Forward for VVC



## Planned Activities

- Pending discussion with FDA, plan to initiate Phase 3 VVC program in 4Q18:
  - Two Phase 3 acute VVC (~300 patients per study → superiority vs. placebo)
  - One Phase 3 recurrent VVC (~300 patients → superiority vs. placebo)

# Invasive Aspergillosis (IA)

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*“Invasive fungal infections will not go away any time soon. Therefore, we need to circumvent resistance to treatment by continued discovery and development of new antifungal agents and strategies.”*

Dr. John Perfect  
Nature Reviews/Drug Discoveries (2017)

# Invasive Aspergillosis: Improving Outcomes in High-Mortality Infection



## Unsatisfactory Clinical Outcomes

Mortality still up to 50%  
Long treatment durations



## Emergence of *A. fumigatus* Resistance



## Need for New Treatment Approaches

## Why Oral Ibrexafungerp?



### Combination therapy may provide improved outcomes

Pre-clinical synergistic activity with azoles  
Clinical benefit of combination therapy reported in literature



### High activity vs. azole-resistant spp. High penetration to the lungs



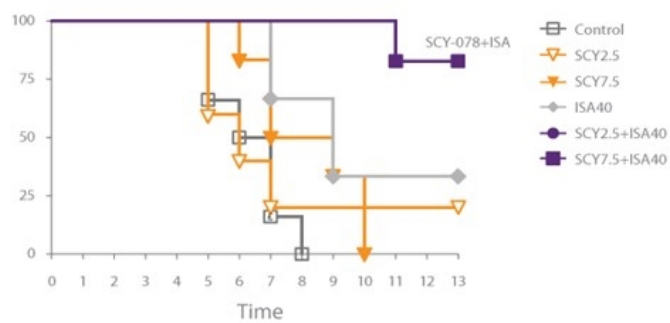
### Optimal for combination therapy

Oral  
Safe and well-tolerated  
Low risk of DDIs

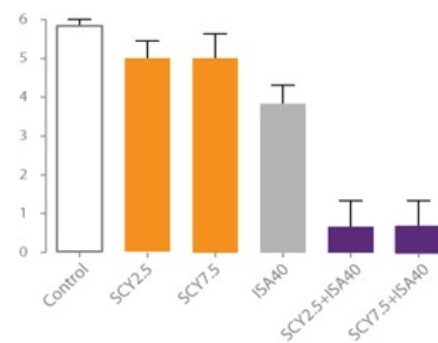
# Ibrexafungerp IA *In Vivo* Data to-Date

- Neutropenic rabbit model of pulmonary aspergillosis evaluating ibrexafungerp alone and in combination with isavuconazole
- Doses: (IV) ibrexafungerp (SCY-078) 2.5, 7.5 mg/kg; (PO) isavuconazole 40 mg/kg for 12 days
- Combination therapy resulted in better efficacy vs. monotherapy for all efficacy parameters, including significantly improved survival and pulmonary infarct score

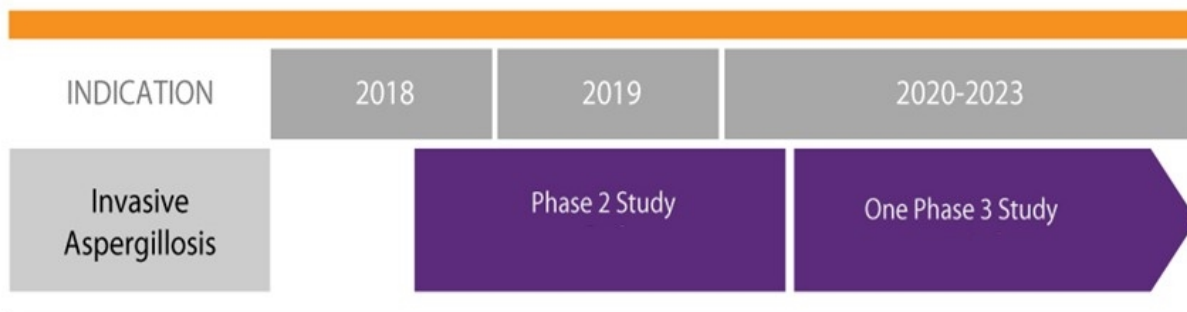
Cumulative Survival Probability (%)



Pulmonary Infarct Score



# Ibrexafungerp IA Development Plan



## Planned Activities

- Phase 2 Oral → ~60 patients
- Oral ibrexafungerp allowing combination for the entire treatment duration
- One Phase 3 required for approval in IA → ~250 IA patients
  - Superiority Design → Comparing oral ibrexafungerp + SoC vs. SoC alone
  - Current standard of care: voriconazole or isavuconazole



# Refractory Invasive Fungal Infections (rIFI)

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*“Invasive fungal infections will not go away any time soon. Therefore, we need to circumvent resistance to treatment by continued discovery and development of new antifungal agents and strategies.”*

Dr. John Perfect  
Nature Reviews/Drug Discoveries (2017)

# Ibrexafungerp rIFI Ongoing Studies

Open-label Phase 3 Studies (**FURI** and **CARES**) vs. historical controls

- **FURI study:** Severe or invasive refractory *Candida* infections
- **CARES study:** Infections caused by *Candida auris*, a pathogen that is often multidrug-resistant and associated with high mortality. Study designed to provide rapid access to oral ibrexafungerp for *C. auris* patients
- **Both studies** have potential eligibility to Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)

# SCYX: Experienced Management

## Leadership

**Positive track record in drug development & antifungal expertise**

**CEO: Marco Taglietti, M.D.**

Schering-Plough, Stiefel, Forest Labs

**CMO: David Angulo, M.D.**

Schering-Plough, Stiefel, Brickell Biotech

**CFO: Eric Francois**

Cowen, Lazard, Topi

**General Counsel: Scott Sukenick**

Cooley

## Board of Directors

**Diverse backgrounds & operating experience in healthcare**

**Guy Macdonald**, Chairman (Tetraphase, Merck)

**Steven Gilman**, PhD (Contrafect, Cubist)

**Ann Hanham**, PhD (BAR Capital, Burrill, FDA)

**David Hastings** (Arbutus Biopharma, Unilife, Incyte)

**Patrick Machado** (Medivation)

**Marion McCourt** (Regeneron, Medivation, Amgen)



# SCYX: Conclusion

## Fulfilling Unmet Needs & Improving Patient Outcomes



