



# WBB Securities, LLC

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## SCYNEXIS, Inc. (NasdaqGM: SCYX)

## Updating Coverage

Updating Coverage by Continuing our Strong Buy Rating  
And Increasing Our 12-Month Price Target to \$15.00

May 4, 2021

### SCYNEXIS Anti-fungal Platform is Corroborated by Pfizer's Purchase of Amplyx

As we have previously mentioned the FDA has scheduled a priority review date on June 1, 2021 for the SCYNEXIS, Inc. (SCYX) New Drug Application (NDA) of ibrexafungerp (SCY-078) (commercial name Brexafemme™), a treatment for vulvovaginal candidiasis (VVC) and the company's lead product. Amplity Health is manufacturing the product with an anticipated launch of 2Q-2021. As a corroborator of the need in this space, Pfizer, Inc. (PFE) acquired Amplyx Pharmaceuticals, Inc. on April 28 with its Phase 2 antifungal, Fosmanogepix, which is intended to treat echinocandin-resistant *Candida* and azole-resistant *Aspergillus*.

Studies of ibrexafungerp for other indications are also underway. Data from a Phase 2 trial of ibrexafungerp for treatment of invasive pulmonary aspergillosis will be available 2H-2021, enrollment is complete in Phase 3 study for recurrent VVC and enrollment is continuing in two open-label Phase 3 studies for refractory invasive fungal infections. All this, providing the company with near-term opportunities for the treatment of multiple invasive fungal infections.

**We believe PFE's acquisition of Amplyx increases the value of SCYX and endorses the scientific and financial merit of its lead product, ibrexafungerp, the company's therapeutic for invasive *Candida* and *Aspergillus* fungal infections. SCYX is on track to be first to market with ibrexafungerp, moreover, ibrexafungerp has been designated as a Qualified Infectious Disease Product (QIDP), which, upon approval, will grant it five years of market exclusivity in addition to the five years of exclusivity as a new chemical entity. We are therefore continuing our Strong Buy rating of SCYX and increasing our 12-month price target to \$15.00.**

Ibrexafungerp is the first oral non-azole treatment, the first in a new class of antifungals in over 20 years and the first new oral treatment in more than 25 years for women suffering from vaginal yeast infections. Ibrexafungerp was granted Fast Track designations from the FDA for the treatment of VVC and prevention of recurrent VVC.

The NDA is supported by positive results from two Phase 3, randomized, double-blind, placebo-controlled, multi-center studies (VANISH-303 and VANISH-306), in which oral ibrexafungerp demonstrated statistically superior efficacy and a favorable tolerability profile in women with VVC.

<b>Current Price</b>	<b>\$7.72</b>
<b>12 Month Target Price</b>	<b>\$15.00</b>
<b>12 Month Trading Range</b>	\$4.20-\$10.15
<b>Market Capitalization (Mil)</b>	\$154.44
<b>Shares Outstanding (Mil)</b>	20.00
<b>Avg. Daily Volume</b>	450,727
<b>L. T. Debt (Mil)</b>	14.00*
<b>Dividend/Yield</b>	N/A
<b>Book Value P/S</b>	\$1.16
<b>NASDAQ Composite</b>	13,895.12
<b>S&amp;P 500</b>	4,192.66
Historical Performance/Price and Volume Chart - Page 7 Convertible Debt*	

## Valuation

### Rating Legend:

**Strong Buy** – Should be aggressively purchased.

**Buy** - Should be purchased on market weakness.

**Hold** - Fairly valued.

**Sell** - Stock should be sold on market strength.

**Sell Short** - Should be aggressively sold.

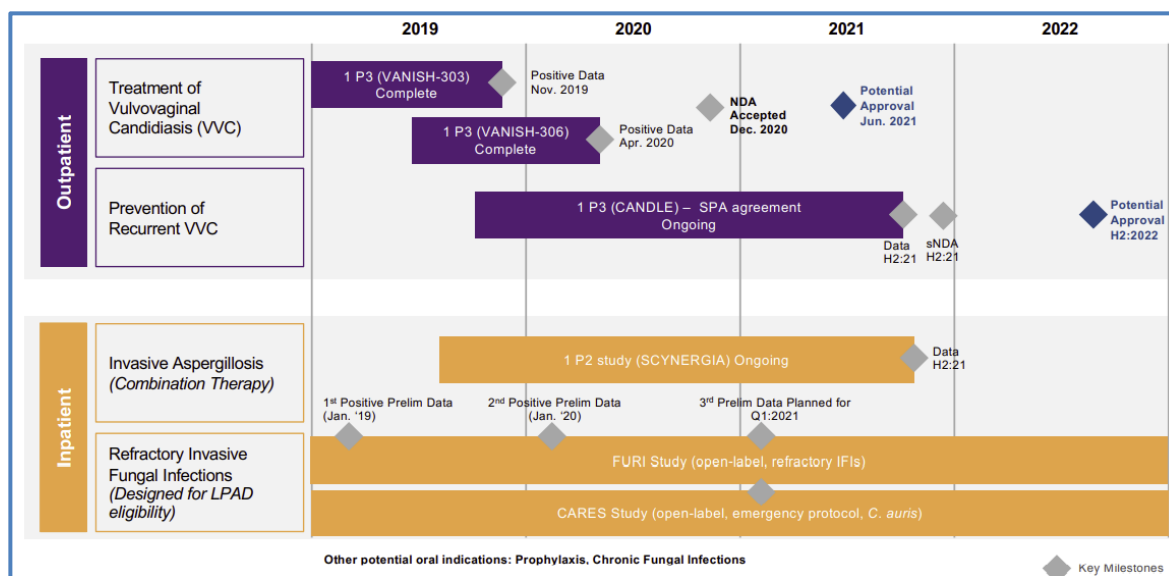
**Speculative Buy** – For aggressive accounts only.

**Core Holding** – Essential holding of a long-term account.

We are updating SCYX based on the continuous progress of Ibrexafungerp, a therapeutic we consider to be one of the most important anti-infective innovations in a generation. We believe that women have been suffering from VVC (again, a devastating genital fungal infection for which there are only minimally effective treatments) as such, this product’s FDA approval will be a critical step in addressing this severe indication.

Our thesis regarding Ibrexafungerp has not changed in considering other numerous potential indications that we feel can be addressed by this important therapeutic. We also still believe that we are seeing a broad decline in the effectiveness of other fungal therapies as deadly pathogens have gained resistance. As a result, using a discounted cash flow model on contemplated Ibrexafungerp sales with a discount rate of 15%, produces a valuation of \$15.00 per share. Therefore, we are continuing our Strong Buy rating with a new and increased 12-month price target of \$15.00.

## Pipeline



Source: SCYNEXIS, Inc. Web Site May 3, 2021

## Ibrexafungerp (SCY-078)

### Clinical Trial Results

Enrollment is complete in the Phase 3 CANDLE study of ibrexafungerp for the prevention of recurrent VVC, for which there is no approved therapy in the U.S. SCYX expects the last-patient last-visit by the EOY-2021 with top-line results and a supplemental NDA submission in the 1H-2022, and potential approval in late 2022.

Enrollment is continuing in two open-label Phase 3 studies (FURI and CARES) for refractory invasive fungal infections (rIFI). SCYX presented positive data from its third interim analysis of the FURI study and first interim analysis of the CARES study on March 2, 2021. Consistent with two prior interim analyses, the FURI results confirm positive clinical activity of oral ibrexafungerp in patients with difficult-to-treat, severe, mucocutaneous and invasive fungal infections, including those caused by resistant strains. In total, oral ibrexafungerp showed clinical benefits in 64 out of 74 patients (86.5%), with 46 patients achieving a complete or partial response and 18 patients with stable disease. The first interim analysis of CARES study showed strong clinical activity of oral ibrexafungerp in patients with invasive candidiasis (IC) and candidemia due to *Candida auris*, with 8 out of 10 patients experiencing a complete response. The results support continued enrollment in both open-label Phase 3 studies, with potential future submissions under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), which is a tool implemented by the FDA to help with approval of antibacterial and antifungal drugs to treat serious and life-threatening infections in a limited population of patients with unmet needs.

Dosing is continuing in the Phase 1 trial of the liposomal IV formulation of ibrexafungerp. The study is being conducted in South Africa and dosing started in March 2021.

Enrollment is continuing in the Phase 2 SCYNERGIA study for patients with invasive aspergillosis. SCYNERGIA is evaluating oral ibrexafungerp in combination with voriconazole for the treatment of patients with this high-mortality infection. Top-line data from this study is expected by the EOY-2021.

In a Phase 3 trial (VANISH-303) to evaluate the efficacy and safety of oral ibrexafungerp versus placebo in subjects with acute vulvovaginal candidiasis, 376 female patients (age 12 and older) with acute VVC and 286 patients with a culture-confirmed infection) were randomized 2:1 to receive either ibrexafungerp or a placebo. Ibrexafungerp achieved superiority versus placebo in this trial's primary endpoints with a clinical cure at Test of Cure (TOC) visit of 50.5% and fewer than one sign and symptoms (swelling, redness, fissures, burning, itching, irritation) of 64.4% with a p-score of 0.001. Ibrexafungerp was generally safe and well-tolerated with mostly GI Treatment-Emergent Adverse Events (TEAE) that were predominantly mild and of short duration.

Topline results of the VANISH-306 Phase 3 trial were similar to those of the VANISH-303 trial. 63.3% of ibrexafungerp-treated patients met the primary endpoint of clinical cure at the Day-10 Transition of Care (TOC) visit, following a single-day administration of two doses of 300mg administered 12 hours apart. 58.5% of ibrexafungerp-treated patients met the secondary endpoint of mycological eradication at TOC visit. 72.3% were clinically improved at TOC visit,

and 73.9% of ibrexafungerp-treated patients had complete symptom resolution at the Day-25 follow-up visit.

## **Ibrexafungerp (Brexafemme) Commercial Prospects**

**VulvoVaginal Candidiasis** - In a July 2020 KOL presentation the company estimated that the peak U.S. net sales potential for ibrexafungerp in the VVC indication would be \$400 million to \$600 million. VVC afflicts 75% of women at least once in their lifetime -- 9 million women in the U.S. and 138 million women worldwide annually. 50% of women will have a recurrence and 8% will have 3+ episodes in a year, which qualifies as recurrent VVC (rVVC). Ibrexafungerp is a convenient, oral medication. A one-day 600mg dose is indicated for treatment of an active infection and a one-day 600mg dose once a month for six months for prevention.

The current preferred treatment for VVC is fluconazole. It has some negative aspects, one being a risk of miscarriage between 7 and 23 weeks of pregnancy. After 6 months weekly fluconazole suppression, 50%-60% of women have a recurrence. Among 191 women with rVVC, the median duration of fluconazole suppressive therapy was 16 months during 3 years of follow-up. By age 50, 25% of women in the US report experiencing rVVC lasting 1-4 years.

**Invasive Candidiasis** -- IC is a serious, often life-threatening infection caused by *Candida* species. It occurs most frequently in highly vulnerable, immunocompromised patients. An article in BMC Infectious Diseases reports IC is the most common fungal disease among hospitalized patients worldwide. According to conservative estimates, IC affects more than 250,000 people worldwide every year and is the cause of more than 50,000 deaths. IC is widely reported in critically ill patients in the intensive care unit (ICU). The risk factors for IC included granulocytopenia, stem cell transplant, organ transplants, broad-spectrum antimicrobial agents, central venous catheterization, total parenteral nutrition, length of stay in the ICU, surgery, advanced life support, and aggressive chemotherapy. With the increase of in related research, there have been reports showing that in people over 65 years old, diabetes mellitus and chronic renal failure are identified as risk factors for patients with IC. According to the CDC, despite existing antifungal agents, mortality in this high-risk patient population remains high at ~25%. Additionally, the increasing emergence of drug-resistant *Candida* strains has created an urgent need for new treatments.

The CDC also has listed fluconazole-resistant *Candida* as a serious threat requiring prompt and sustained action and has also identified a rise in echinocandin resistance, especially among *Candida glabrata*. The CDC has issued an extraordinary alert for healthcare facilities and providers to be on the lookout for patients with *C. auris*, a multidrug-resistant strain with high mortality of ~60%.

SCYNEXIS out-licensed the rights to ibrexafungerp for the Greater China region to Hansoh Pharmaceutical Group Company Limited (3692.HK) in February 2021. SCYX received a \$10 million upfront payment and is eligible to receive development and commercial milestone payments of up to \$112 million, plus low double-digit royalties on net sales. The company also raised \$85 million in a public offering of common stock, prefunded warrants and warrants on December 17, 2020.

## Risks

In addition to the risks normally anticipated in a development-stage biotechnology company, the following that are specific to this company.

\$16 million of SCYX 6.0% senior convertible notes that were issued to Puissance Capital Management are due in 2025, and an additional \$10 million of 6.0% senior convertible notes held by Puissance are due 2026. Covenants under the company's convertible notes may require SCYX to repay the notes in the event of default, which could have a materially adverse effect on its business.

A significant use of antifungal drugs is based on the presence of symptoms before diagnosis. If new quick response diagnostic systems become widely used, the number of treatments using antifungal drugs could decrease, having a detrimental effect on the potential market for ibrexafungerp.

Merck & Co. established the intellectual property rights related to ibrexafungerp. If they were not established with sufficient scope, intellectual property rights to ibrexafungerp could be constrained.

As of December 31, 2020, SCYX had an accumulated deficit of approximately \$326.6 million and cash equivalents of \$93.0 million, which could hamper achieving break-even and/or profitability.

## Management

**Marco Taglietti, M.D. President and Chief Executive Officer** since April 2015 and a member of the Board of Directors since November 2014. He became SCYNEXIS president in September 2015. Prior to SCYNEXIS, Dr. Taglietti held executive positions at Forest Laboratories, Inc. and the Forest Research Institute until it was purchased by Actavis. Dr. Taglietti also was Senior Vice President, Head of Global Research and Development at Stiefel Laboratories, Inc. He also worked at Schering-Plough Corporation for 12 years and Marion Merrell Dow Research Institute. Dr. Taglietti attended University of Pavia, where he received his board certifications and medical degree.

**David Angulo, M.D. Chief Medical Officer** since June 2015. Before joining SCYNEXIS, Dr. Angulo was the Vice President, Research and Development at Brickell Biotech, Inc. and held executive positions at Stiefel Laboratories in the clinical and medical departments. He also led anti-infective development programs at Schering-Plough Research Institute. He received his post-graduate degrees in infectious diseases and pediatrics, along with his medical degree, from the Universidad de Guadalajara, Mexico.

**Eric Francois, Chief Financial Officer** since November 2015. Previously, he worked at Topi, Inc., a technology startup, as the Chief Operating Officer. Mr. Francois spent six years at Lazard Ltd. as a Director in the Equity Capital Markets Group. He also worked at Cowen and Company in the Equity Capital Markets and Convertible Debt Groups. He received his Bachelor's degree

in Economics and Business Administration with a Master's Degree in Marketing from Pantheon-Sorbonne University.

**Scott Sukenick, General Counsel** since November 2017. Prior to SCYNEXIS, Mr. Sukenick was focusing on life sciences litigation and strategic intellectual property at Cooley LLP. Before Cooley LLP, Mr. Sukenick was at Patterson Belknap Webb & Tyler LLP, representing pharmaceutical and medical device companies in patent litigation. Mr. Sukenick started his career focusing on commercial litigation and intellectual property at Simpson Thacher & Bartlett LLP. Mr. Sukenick earned his B.S. in Biology and his B.A. in Chemistry from Duke University and his J.D. from Harvard University.

**Nkechi Azie, M.D., FIDSA, Vice President, Clinical Development and Medical Affairs** since June 2019. Prior experience includes: Senior Vice President of Medical Affairs at The Medicines Company, Senior Director of Medical Affairs at Astellas Pharma, Director of Anti-infective Clinical Development for Pfizer, Inc. Dr. Azie is board certified in internal medicine, clinical pharmacology, and infectious disease and was elected for Infectious Diseases Society of America (IDSA) Fellowship. She holds an executive M.B.A. from the University of Notre Dame Mendoza College of Business, a Bachelor of Medicine, a Bachelor of Surgery and a B.S. from the University of Nigeria College of Medicine and she conducted a medical residency and subspecialty training at Indiana University Medical Center.

**Jim Maffezzoli, Vice President, Marketing and Sales** - Prior experience includes: Senior Vice President of Marketing at Viveve Medical, commercial leadership roles in Urology and Women's Health at Allergan plc, Exeltis USA, Inc. (a division of the global pharmaceutical group Insud Pharma) and Pfizer Inc. Mr. Maffezzoli holds an M.B.A. from the J.L. Kellogg Graduate School of Management at Northwestern University, and a B.A. in Political Economy from Princeton University.

**Rajeshwar Motheram, Ph.D., Senior Vice President, Pharmaceutical Development and Supply Chain** since October 2015. Prior experience includes: research and management positions at The Medicines Company, Bristol-Myers Squibb, DuPont Pharmaceuticals and Baxter International. Over the course of his career, he developed several commercial products in multiple therapeutic areas. Dr. Motheram is a co-inventor on various patents concerning novel pharmaceutical compositions and has co-authored manuscripts published in peer-reviewed journals. Dr. Motheram holds a Ph.D. in Pharmaceutics from the University of the Sciences, Philadelphia College of Pharmacy, an M.S. in Pharmaceutics from the University of Mississippi and a B.S. in Pharmacy from Kakatiya University.

## Historical & Future EPS Performance

EPS	2019	2020	2021
Q1	(0.46)A	(0.07)A	(0.75)E
Q2	(1.58)A	(0.64)A	(0.80)E
Q3	(1.45)A	(0.28)A	(0.90)E
Q4	(6.09)A	(4.16)A	(0.95)E
Year	(9.58)A	(5.15)A	(3.40)E
P/E	NM	NM	NM
EPS Growth	NM	NM	NM
FY Rev. (Mil)	1.21A	0.0A	1.0E
<b>FY:DEC</b>			

### Other companies mentioned in this report:

Amplify Health (Private)  
 Hansoh Pharmaceutical Group Company Limited (3692.HK)  
 Pfizer, Inc. (PFE)

## Price and Volume

WBB Initiated Coverage of SCYNEXIS on 12/29/15



1	Morning Note 07/11/18
2	Morning Note 01/31/19
3	Updated coverage of SCYX on 11/07/19 at \$1.28 with a Strong Buy Rating and a 12-month price target of \$10.00

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	Percentage of Covered Securities	Percentage of Banking Clients
Buy	78.3%	17.4%
Hold	17.4%	0%
Sell	04.3%	0%

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