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SCYNEXIS Reports Full Year 2016 Financial Results and Provides Company Update

JERSEY CITY, N.J., March 13, 2017 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ:SCYX), a drug development company committed to the development and commercialization of novel anti-infectives to address significant unmet therapeutic needs, today reported financial results for the year ended December 31, 2016, and provided an update on recent operational and clinical developments.

"2016 was rich in achievements for SCYNEXIS, and we accomplished many corporate and clinical development milestones in a short period of time," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "We've continued to make progress in developing SCY-078, a novel antifungal triterpenoid class, for the treatment of invasive, often life-threatening and drug-resistant fungal infections that are rapidly becoming a global health crisis. We also strengthened our financial position in 2016 to focus on the continued advancement of SCY-078, our lead program."

2016 Corporate Accomplishments

- Successfully completed an underwritten public offering raising gross proceeds of $22.5 million and the closing of a term loan raising an additional $15 million in gross proceeds. These transactions have strengthened our financial position, which we expect will extend our cash runway into early 2019.

- Received designation as a Small and Medium Sized Enterprise (SME) by the European Medicines Agency (EMA), making us eligible to receive financial incentives, reduced regulatory fees and waivers, and scientific advice and other assistance from EMA personnel through the clinical development process.

2016 SCY-078 Update Development Progress

- Completed two Phase 2 studies of oral SCY-078 in separate patient populations with *Candida spp.* infections that provided evidence of overall anti-*candida* activity and a promising safety profile:

  - In a Phase 2 study evaluating oral SCY-078 in patients with vulvovaginal candidiasis (VVC), we observed numerically higher clinical cure rates at test-of-cure and fewer recurrences of VVC at the four-month follow-up when compared to the standard of care (oral fluconazole).

  - In a Phase 2 study evaluating the pharmacokinetics, safety and tolerability of oral SCY-078 as an oral step-down treatment in patients with invasive candidiasis, we identified the daily oral SCY-078 dose that achieves the intended plasma exposure for

efficacy and was well-tolerated.

- On March 2, 2017, the U.S. Food and Drug Administration (FDA) informed us to hold the initiation of any new clinical studies with the intravenous (IV) formulation of SCY-078. Ongoing and future clinical development using the oral formulation of SCY-078 are unaffected by this regulatory action. We are working closely with the FDA to review the pre-clinical and clinical data supporting the use of a suitable IV formulation and dose regimen of SCY-078 to test in subsequent studies. The upcoming meeting with the FDA is scheduled for the second quarter of 2017.

- Completed two additional Drug-Drug Interaction (DDI) studies, demonstrating the low potential of SCY-078 to cause clinically relevant DDIs, an attribute that differentiates this novel agent from azoles.

- Completed three-month toxicology studies that support the longer duration of oral treatment (up to 90 days) in our subsequent studies.

- The FDA granted Orphan Drug Designation (ODD) to SCY-078 for the treatment of both invasive *Aspergillus* and *Candida* infections, as well as Fast Track and Qualified Infectious Disease Product (QIDP) designations for the IV formulation of SCY-078 for the treatment of invasive candidiasis and invasive aspergillosis. Fast Track and QIDP designations for the oral formulation of SCY-078 were previously granted.

SCY-078 and Recent Corporate Updates

- Opened sites in the U.S. to evaluate SCY-078 in patients with invasive **FU**ngal infections that are **R**efractory to, or are **I**ntolerant of, standard therapies (the **FURI** study), for which SCY-078 has the potential to provide a differentiated treatment option. We expect enrollment for patients receiving the oral administration of SCY-078 to commence in the first half of 2017.

- In February 2017, preclinical research done at Case Western Reserve School of Medicine showed that SCY-078 was effective *in vitro* against *Candida auris*, a life-threatening and multidrug-resistant fungus. These findings were published online and in an upcoming issue of *Antimicrobial Agents and Chemotherapy*. Researchers evaluated the activity of SCY-078 against 16 different *C. auris* isolates and results showed potent activity of SCY-078 against all strains at concentrations indicative of potential clinically-relevant effect.

- Submitted SCY-078 data presentations and publications at multiple medical meetings throughout the course of the year, including the European Congress of Clinical Microbiology and Infectious Diseases 2017 (ECCMID), ASM Microbe 2017 and ID Week 2017.

- Strengthened our commercial, strategy, operations and business development experience with the addition of industry veteran Marion McCourt, former Chief Operating Officer of Medivation, to the SCYNEXIS Board of Directors.

Full Year 2016 Financial Results

Cash and cash equivalents and short-term investments totaled $58.6 million as of December 31, 2016.

Research and development expenses increased to $20.1 million in 2016, compared to $16.4 million in 2015. The increase of $3.7 million, or 23%, was primarily the result of the expansion of our development programs for SCY-078 in 2016 including the completion of two Phase 2 studies, extension of the Phase 1 IV program, and the completion of three-month toxicology studies and two DDI studies.

Selling, general and administrative expenses decreased to $8.0 million from $12.2 million for the year ended December 31, 2015. The decrease of $4.2 million, or 34%, was primarily the result of the decrease in severance, retention and stock compensation expense recognized during the year ended December 31, 2015.

Loss from operations in 2016 was $27.8 million, compared to a loss from operations of $28.3 million in 2015. The $0.5 million decrease in the loss from operations between the two periods was due to a $3.7 million increase in research and development expense, offset by a decrease in selling, general and administrative expense of $4.2 million.

Total other expense (income) increased to $2.2 million in 2016 due to a $1.9 million non-cash loss recorded on the adjustment in the fair value of the warrant liability.

Net loss attributable to common stockholders in 2016 was $30.0 million, or $1.58 per share. This compares to net loss attributable to common stockholders in 2015 of $32.6 million, or $2.68 per share.

About SCYNEXIS, Inc.

SCYNEXIS is a drug development company committed to the 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 IV drug for the treatment of several fungal infections, including serious and life-threatening invasive fungal infections. For more information, visit www.scynexis.com.

Forward Looking Statement

Statements contained in this press release, including but not limited to the statements, regarding Company’s future cash position and the timing of the next meeting with the FDA to discuss the data and agree on subsequent studies, 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. These risks and uncertainties include, but are not limited, to: risks inherent in SCYNEXIS' ability to successfully develop SCY-078, including SCYNEXIS' ability to resolve the FDA’s concerns to lift the clinical hold and obtain FDA approval for SCY-078; the expected costs of studies and when they might begin or be concluded; and SCYNEXIS' reliance on third parties to conduct SCYNEXIS' clinical studies. These and other risks are described more fully in SCYNEXIS' filings with the Securities and Exchange Commission, including without limitation, its most recent Annual Report on Form 10-K under the caption "Risk Factors" 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.

STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Years Ended December 31, 2016	2015
Revenue	$ 257	$ 257
Operating expenses:		
Research and development, net	20,076	16,440
Selling, general and administrative	7,998	12,166
Total operating expenses	28,074	28,606
Loss from operations	(27,817)	(28,349)
Other expense (income):		
Amortization of deferred financing costs and debt discount	100	—
Interest income	(185)	—
Interest expense	351	(11)
Warrant liability fair value adjustment	1,906	—
Total other expense (income)	2,172	(11)
Loss from continuing operations before taxes	(29,989)	(28,338)
Income tax benefit	—	—
Loss from continuing operations	(29,989)	(28,338)
Loss from discontinued operations, net of tax	—	(4,285)
Net loss	$ (29,989)	$ (32,623)
Loss per share attributable to common stockholders - basic and diluted		
Continuing operations	$ (1.58)	$ (2.33)
Discontinued operations	—	(0.35)
Net loss per share - basic and diluted	$ (1.58)	$ (2.68)
Weighted average common shares outstanding:		
Basic and diluted	19,035,299	12,163,559

SCYNEXIS, INC.
BALANCE SHEETS
(in thousands)

	December 31, 2016	December 31, 2015
Cash and cash equivalents	$ 35,656	$ 46,985
Short-term investments	22,930	—
Total current assets	59,327	48,437
Total assets	59,792	49,273
Total current liabilities	3,717	6,664
Total liabilities	24,973	7,324
Total stockholders' equity	34,819	41,949
Total liabilities and stockholders' equity	$ 59,792	$ 49,273

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