

SCYNEXIS

SCYX : NASDAQ : US\$8.20

BUY

Target: US\$18.00

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COMPANY STATISTICS:

Shares Out (M): 9.4
 Market Cap (M): US\$77.0
 52-week Range: US\$8.07 - 9.84

EARNINGS SUMMARY:

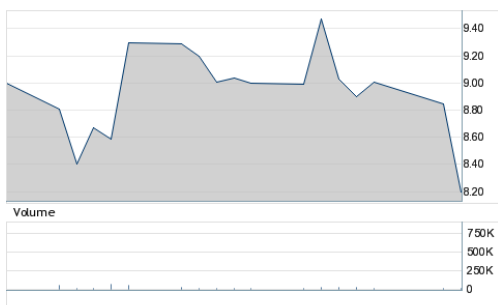
FYE Dec	2013A	2014E	2015E
Revenue:	16.9	17.0	17.0
EPS:	--	(4.82)	(1.52)

Revenue:	Q1	--	4.0	--
	Q2	--	4.5	--
	Q3	--	4.0	--
	Q4	--	4.5	--
Total		16.9	17.0	17.0
EPS:	Q1	--	(1.23)	--
	Q2	--	(1.16)	--
	Q3	--	(1.24)	--
	Q4	--	(1.20)	--
Total		--	(4.82)	(1.52)

SHARE PRICE PERFORMANCE:

Scynexis, Inc. (NASDAQ: SCYX)

May 28, 2014 Open: 8.830 High: 9.015 Vol: 11,929
 Time: 16:00 Last: 8.200 Low: 8.200 Chg: -0.650 (-7.34%) ▼



Source: Interactive Data Corporation

COMPANY DESCRIPTION:

Headquartered in Durham, North Carolina, SCYNEXIS is a pharmaceutical company committed to the discovery, development and commercialization of novel anti-infectives to address significant unmet therapeutic needs.

All amounts in unless otherwise noted.

Life Sciences -- Biotechnology

BUILDING A BETTER ANTIFUNGAL: INITIATING WITH BUY, \$18 TARGET

Investment recommendation

Initiating coverage with a BUY and \$18 target, based on the potential of lead Ph2 ready drug SCY-078 for systemic fungal infections. We think SCY-078 has significant potential for systemic candidiasis and aspergillosis. SCY-078 has good preclinical potency data and little to no cross-resistance with current standard of care drugs. SCY-078 has good Ph1 safety/tolerability and ease of use driven by oral dosing. We model peak US sales of SCY-078 at ~\$280MM; our \$18 target is driven by a pNPV analysis.

Investment highlights

- **SCY-078: significant potential for invasive fungal infections.** We think SCY-078 has the potential to become an important treatment option for systemic fungal infections based on good efficacy, safety and favorable resistance profile. We think the market for invasive antifungal therapies is growing due to rising numbers of BMT transplants and chemotherapy patients.
- **We believe the upcoming Ph2 trial of SCY-078 in invasive fungal infections has a high chance of success (data Q4/15 or Q1/16).** We see preclinical potency data as very positive with high predictive value for upcoming Ph2 clinical trials. We also view data from the seven Ph1 trials of SCY-078 as positive. SCY-078's main side effect appears to be GI upset and rare transient liver enzyme elevations.
- **We believe rising incidence of resistance to current therapies and ease-of-use associated with oral formulation will drive uptake.** Resistance for standard first-line azole class drugs is approaching 30% of invasive candida strains, and resistance to echinocandins, the gold standard treatment, is approaching 15% in some areas. We believe infectious disease MDs want additional treatment options without cross-resistance to these current Tx's. We model peak US sales of SCY-078 at ~\$280MM.

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The recommendations and opinions expressed in this research report accurately reflect the Investment Analyst's personal, independent and objective views about any and all the Designated Investments and Relevant Issuers discussed herein. For important information, please see the Important Disclosures section in the appendix of this document.

INVESTMENT THESIS

We think SCYNEXIS' Ph2-ready SCY-078 could become a key therapeutic option for the treatment of invasive fungal infections. SCY-078 is a first-in-class enfumifungin antifungal that works by interfering with the production of fungal cell walls. The drug specifically inhibits the synthesis 1,3 beta glucan, the same mechanism as the gold standard echinocandin class of drugs. We believe this gives SCY-078 strong scientific rationale for success against systemic fungal infections. SCY-078 is thought to target a different structure on the 1,3 glucan synthase enzyme, however, which could prevent cross-resistance with echinocandins. SCY-078 is currently formulated for oral delivery, and the company is working on an IV formulation for maximal dosing flexibility.

We believe there is a significant unmet need for new treatment options for invasive fungal infections (e.g., candidiasis and aspergillosis) as resistance emerges. The two major types of drug classes used to treat systemic fungal infections, azoles (oral) and echinocandins (IV), are both facing increasing prevalence of resistance and strains with reduced susceptibility. New treatment guidelines have demoted azoles below first-line treatment of candidiasis due to the high prevalence of azole resistant (30-50% across various studies). Further, echinocandin resistance rates in candidiasis are approaching 15% as lower susceptibility strains such as *C. glabrata* become more prevalent compared to high susceptibility strains like *C. albicans*. As such, new treatment options with differential resistance profiles are needed as resistant strains emerge and spread.

We think SCY-078 will prove to have an excellent efficacy profile: clinically meaningful potency as well as little cross-resistance with current therapies. Pre-clinical studies have shown SCY-078 to have similar potency in models of systemic candidiasis and aspergillosis as echinocandins, and likely better potency than azoles. Cross-resistance studies have shown that *Candida* and *Aspergillus* strains with resistance to azoles maintained susceptibility to SCY-078, likely due to SCY-078's differential binding on the 1,3 beta glucan synthase versus echinocandins.

We also think SCY-078 will prove to have a very clean safety profile, based on extensive Phase 1 trials that show little to no safety signal. SCYNEXIS had previously licensed SCY-078 development and commercialization rights to Merck, which ran an extensive Phase 1 program on the drug, involving seven different safety trials in healthy volunteers. We believe the safety database amassed is very clean and comprehensive, and suggests SCY-078 will be at least as safe and tolerable as azole and echinocandin class drugs. We believe '078 will be far more safe and tolerable than older generation antifungals like amphotericin. Further, we think the potential for oral delivery will allow for more flexibility in use, making the drug appropriate as a step-down therapy following echinocandins or as prophylaxis.

We think the market for a novel systemic antifungal, especially one with the potential to constitute an oral step down therapy, is significant, representing peak sales of \$280M, and possible higher based on very conservative pricing. Given the need for new treatment options due to growing numbers of post-transplant and chemotherapy patients that are susceptible to infections, increasing resistance and rising prevalence of strains with lower susceptibility to current standard of care, as well the utility of a potential non-azole step-down therapy, we think SCY-078 could reach peak sales of ~\$20MM in the post-transplant market and over \$250MM in the chemotherapy market.

We also view SCYNEXIS' pipeline of earlier-stage antifungals as driving value. SCYNEXIS has a platform of enfumifungin derivatives with differential PK/PD that could potentially yield additional important new drug candidates for the treatment of invasive fungal infections. SCYNEXIS also has a cyclophilin inhibitor pipeline that could generate new anti-viral and anti-inflammatory drug candidates.

INVESTMENT RISKS

Clinical risk - SCYNEXIS may not be successful in its clinical trials of SCY-078: efficacy or safety could prove to be problematic. We note that SCYNEXIS has not yet generated efficacy data in localized or invasive fungal infections in humans. While preclinical models of systemic candida and aspergilla infections have been extremely predictive of clinical success, there is still a chance that SCY-078 may prove to have inadequate potency against invasive infections in humans. Further, despite seven Phase 1 trials run by former partner Merck that showed good tolerability, additional testing in sicker patients could show more severe instances or higher rates of the most commonly observed adverse events, namely GI distress and mild liver enzyme elevation.

Regulatory risk - There is no guarantee SCYNEXIS can obtain approval for SCY-078 using the abbreviated approval path FDA appears amenable to currently. Based on conversations with FDA, SCYNEXIS believes it has been allowed an expedited development path that allows the company to bypass a Phase 2a in esophageal candidiasis. This is related to the drug's QIDP designation (per the GAIN act to encourage the development of new anti-infective therapies). This designation should allow for expedited trials and registration for the drug candidate, but should FDA reconsider (due to new clinical data or a change in regulatory policy), the agency could slow registration by requiring additional clinical trials or safety data before approval. Even then, there is no guarantee that the agency will grant a timely approval.

Commercial risk - SCY-078 will be facing competition from established branded drugs as well as established drug classes that have gone or shortly will go generic. SCYNEXIS' operating results will suffer if they fail to successfully compete with the other biotech and pharma companies (Merck, Pfizer and Astellas) that are currently commercializing echinocandins for the treatment of invasive fungal infections. Most of the azole class drugs have already gone generic and therefore are readily available for very low prices. Clinicians already have significant experience and comfort with these drugs. Further, echinocandins will be going generic over the next decade, shortly after potential approval of SCY-078. This is all in the context of in-patient use for these drugs, and hospitals are notoriously price sensitive due to reimbursement practices and methodologies. As such, SCY-078 could face considerable commercial challenges.

Commercial/partnership risk - SCYNEXIS may face significant commercialization challenges if it chooses to self-promote SCY-078, but also has no guarantee of partnership interest. SCYNEXIS has no track record of launching or commercializing a drug itself and has no members of management at this point that have successfully done so. Further, the number of companies that have been committed to bringing new anti-infective drugs to market have been limited (although this may change with new incentives in the GAIN act). As such, development or commercialization partnership opportunities may be limited.

Financing risk - SCYNEXIS may not have enough cash to fund clinical development and corporate operations through to SCY-078 approval. SCYNEXIS currently has \$40MM cash, which is sufficient to generate proof of concept data but may not be enough to generate sufficient data for an acceptable registration filing (NDA) with the FDA. As such, we believe SCYNEXIS may raise money by issuing shares in order to fund additional clinical trials and finance operations.

VALUATION

We have built our valuation of SCYNEXIS using a probability-weighted NPV model of peak sales.

Potential upside to valuation

We see the following as potential drivers of upside to our model:

- **Stronger than expected Phase 2a data (either efficacy or safety) from SCY-078.** Should SCY-078 generate stronger efficacy/potency data than expected, it could mitigate further clinical development, regulatory and commercial risk, driving value to the share price.
- **Partnership for other pipeline candidates.** SCYNEXIS has a pipeline of drug candidates from both its cyclophilin inhibitor platform and its modified enfumifungin platform. Should SCYNEXIS strike a partnership or license agreement around these assets, the company may be able to monetize the potential of these molecules.

Potential downside to valuation

As with all companies in commercial and clinical development, there always exists the risk of failed or inconclusive clinical trials, slower-than-expected commercial launches, or lower-than-expected peak sales, which could lead to downward pressure on the stock. For more detailed risks, see our “Investment risks” section.

Figure 1: SCYNEXIS valuation

Drug name	Indication	Status	Launch	Years to		Success	Sales (US\$m)	Royalty	Profitability	NPV (US\$)
				Launch	Launch plus 7					
SCY-078	Post transplant invasive fungal infection	Phase 2	2018	4	11	55%	23.0	100%	90%	1.55
SCY-078	Post chemo invasive fungal infection	Phase 2	2018	4	11	55%	247.8	100%	90%	16.68
Total										18.23

Source: Company reports and Canaccord Genuity estimates

Figure 2: SCY-078 revenue projections

	2017	2018	2019	2020	2021	2022	2023	2024	2025
HSCT model									
US population	0.7%	322.8	325.1	327.3	329.6	331.9	334.2	336.6	338.9
HSCT procedures		22,452	23,288	24,154	25,053	25,985	26,952	27,955	28,995
Incidence	3.0%	0.000070	0.000072	0.000074	0.000076	0.000078	0.000081	0.000083	0.000086
HSCT patients prophylaxed/empirically Tx		3,713	4,044	4,404	4,796	5,223	5,689	6,195	6,747
% of all HSCT patients	5.00%	16.54%	17.36%	18.23%	19.14%	20.10%	21.11%	22.16%	23.27%
078 market share		0.00%	2.00%	5.00%	10.00%	15.00%	20.00%	20.00%	20.00%
Other market share		100.00%	98.00%	95.00%	90.00%	85.00%	80.00%	80.00%	80.00%
HSCT patients on '078		0	88	240	522	853	1,239	1,349	1,470
Gross cost	2.0%	4,500.00	4,590.00	4,681.80	9,000.00	9,180.00	9,363.60	9,550.87	9,741.89
Net cost	10.0%	4,050.00	4,131.00	4,213.62	8,100.00	8,262.00	8,427.24	8,595.78	8,767.70
078 HSCT US Revenue		\$0	\$363,853	\$1,010,468	\$4,230,951	\$7,049,940	\$10,441,919	\$11,599,426	\$12,885,244
SOT model									
US population	0.7%	322.8	325.1	327.3	329.6	331.9	334.2	336.6	338.9
SOT procedures		32,861	34,084	35,352	36,667	38,032	39,447	40,915	42,437
Incidence	0.5%	0.000102	0.000105	0.000108	0.000111	0.000115	0.000118	0.000122	0.000125
SOT patients prophylaxed/empirically Tx		3,623	3,946	4,297	4,680	5,097	5,551	6,045	6,583
% of all SOT patients	3.00%	11.03%	11.58%	12.16%	12.76%	13.40%	14.07%	14.77%	15.51%
078 market share		0.00%	2.00%	5.00%	10.00%	15.00%	20.00%	20.00%	20.00%
Other market share		100.00%	98.00%	95.00%	90.00%	85.00%	80.00%	80.00%	80.00%
SOT patients on '078		0	86	234	510	833	1,209	1,317	1,434
Gross cost	2.0%	4,500.00	4,590.00	4,681.80	9,000.00	9,180.00	9,363.60	9,550.87	9,741.89
Net cost	10.0%	4,050.00	4,131.00	4,213.62	8,100.00	8,262.00	8,427.24	8,595.78	8,767.70
078 SOT US Revenue		\$0	\$355,022	\$985,942	\$4,128,258	\$6,878,825	\$10,188,475	\$11,317,886	\$12,572,496
ChemoTx model									
US population	0.7%	322.8	325.1	327.3	329.6	331.9	334.2	336.6	338.9
ChemoTxpatients/ courses		690,969	716,680	743,347	771,007	799,696	829,453	860,317	892,329
Incidence	0.1%	0.002141	0.002205	0.002271	0.002339	0.002409	0.002482	0.002556	0.002633
Chemo patients prophylaxed/empirically Tx		57,134	62,223	67,766	73,802	80,375	87,534	95,331	103,822
% of all SOT patients	3.00%	8.27%	8.68%	9.12%	9.57%	10.05%	10.55%	11.08%	11.63%
078 market share		0.00%	2.00%	5.00%	10.00%	15.00%	20.00%	25.00%	25.00%
Other market share		100.00%	98.00%	95.00%	90.00%	85.00%	80.00%	75.00%	75.00%
Chemo patients on '078		0	1,355	3,690	8,038	13,130	19,066	25,956	28,267
Gross cost	2.0%	4,500.00	4,590.00	4,681.80	9,000.00	9,180.00	9,363.60	9,550.87	9,741.89
Net cost	10.0%	4,050.00	4,131.00	4,213.62	8,100.00	8,262.00	8,427.24	8,595.78	8,767.70
078 ChemoTx US Revenue		\$0	\$5,598,806	\$15,548,610	\$65,103,930	\$108,481,238	\$160,675,454	\$223,108,294	\$247,840,274
Total # '078 Tx courses		0							
Total US '078 revenues		\$0	\$6,317,681	\$17,545,019	\$73,463,139	\$122,410,003	\$181,305,848	\$246,025,606	\$273,298,014

Source: Company reports and Canaccord Genuity estimates

REVENUE MODEL AND FINANCIALS

Our forecast financial model is built on the assumption that SCY-078 will be approved in the US in 2018 for the treatment of invasive/systemic fungal infections caused by candida and aspergilla. We believe the main initial use of these drugs will be for treatment of these conditions after empiric diagnosis. The vast majority of these cases are in patients who have received bone marrow or solid organ transplants or chemotherapy, and are immunosuppressed as a result. We see the overall size of this population of susceptible patients growing due to three factors:

- Increasing numbers of patients receiving chemotherapy due to an expanding and aging population;
- Increasing numbers of bone marrow transplants due to new graft source technology such as cord blood and allogeneic;
- Increasing immunosuppression in these patients due to more aggressive pre-transplant conditioning and post-transplant rejection suppression therapies.

29 May 2014

New treatment guidelines are moving IV echinocandins into first-line position as azole are moved into second-line therapy due to resistance rates approaching 30% in some geographies. Echinocandin resistance itself is growing as less susceptible strains spread, displacing more susceptible strains. As such, we believe a new second/third-line drug option is needed, and that initial use of SCY-078 will be used in this position of the treatment paradigm. We model modest initial sales but peak market share of 20%. We think this peak sales number will also be driven by availability of the IV form of the drug (likely in the 2019/2020 timeframe) as well as increased prophylactic use in patients at particularly high risk.

We very conservatively model potential initial pricing of SCY-078 at \$4,500 per oral treatment course for candidiasis. We think this price will increase to about double when treatment for aspergillosis (~28 days of Tx) is approved. We still view this as very conservative pricing and believe that the price of the drug could reach \$10K-20K per treatment course with supportive mortality and pharmacoeconomic statistics. Overall, we model about \$280M in peak sales around 2025.

SCYX reported current cash of around ~\$40M at the end of March 30, 2014. We believe SCYX has sufficient funding to finish the planned Phase 2a study and conduct additional manufacturing and pre-clinical tox work in preparation for the next stage of development. We think SCYX may consider an equity issue either after Phase 2a data to secure funding for the next SCY-078 trial and registration as well as general operating expenses.

Figure 3: SCYX P&L

	2012A	2013A	Q1/14E	Q2/14E	Q3/14E	Q4/14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
078 HSCT US Revenue	-	-	-	-	-	-	-	-	-	-	-	-	4.2
078 SOT US Revenue	-	-	-	-	-	-	-	-	-	-	-	-	4.1
078 ChemoTx US Revenue	-	-	-	-	-	-	-	-	-	-	-	-	65.1
Other	16.8	16.9	-	-	-	-	16.9	16.9	16.9	16.9	16.9	16.9	-
Product revenues	-	-	-	-	-	-	16.9	16.9	16.9	16.9	16.9	16.9	73.5
Collaboration and licensing revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Contract and grant revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Total revenues	16.8	16.9	4.0	4.5	4.0	4.5	17.0	17.0	17.0	17.0	17.0	16.9	73.5
Cost of goods sold	14.4	16.3	4.1	4.1	4.1	4.1	16.4	-	-	-	-	-	-
Gross Profit	2.5	0.6	(0.1)	0.4	(0.1)	0.4	0.6	17.0	17.0	17.0	17.0	16.9	73.5
R&D expense	8.9	4.4	3.4	3.4	3.4	3.4	13.6	15.0	19.0	25.0	30.0	30.0	30.0
SG&A expense	4.7	4.4	1.1	1.1	1.3	1.5	5.0	7.0	9.0	11.0	11.6	12.1	12.7
Other operating expense	(3.4)	(1.0)	-	-	-	-	-	-	-	-	-	-	-
Total operating expense	10.3	7.8	4.5	4.5	4.7	4.9	18.6	22.0	28.0	36.0	41.6	42.1	42.7
Operating income	(7.8)	(7.2)	(4.6)	(4.1)	(4.8)	(4.5)	(18.0)	(5.0)	(11.0)	(19.0)	(24.6)	(25.3)	30.7
Amort'n of deferred financing costs, debt discount	(2.9)	(3.5)	(0.9)	(0.9)	(0.9)	(0.9)	(3.5)	-	-	-	-	-	-
Interest exp beneficial conversion feature	-	(10.8)	(2.7)	(2.7)	(2.7)	(2.7)	(10.8)	-	-	-	-	-	-
Interest expense - related party	(0.7)	(0.9)	(0.2)	(0.2)	(0.2)	(0.2)	(0.9)	-	-	-	-	-	-
Interest expense	(0.2)	(0.2)	(0.0)	(0.0)	(0.0)	(0.0)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	-	-
Derivative fair value adjustment	0.2	(7.9)	(2.0)	(2.0)	(2.0)	(2.0)	(7.9)	(7.9)	(7.9)	(7.9)	(7.9)	-	-
Other Income	0.0	-	-	-	-	-	-	-	-	-	-	-	-
Pre-tax income	(3.7)	(23.3)	(5.8)	(5.8)	(5.8)	(5.8)	(23.3)	(8.1)	(8.1)	(8.1)	(8.1)	-	-
Net income (loss)	(11.5)	(30.5)	(10.4)	(9.9)	(10.6)	(10.3)	(41.3)	(13.1)	(19.1)	(27.1)	(32.6)	(25.3)	30.7
Basic EPS	(1.73)		(1.23)	(1.16)	(1.24)	(1.20)	(4.82)	(1.52)	(2.21)	(3.11)	(3.73)	(2.88)	3.48
Diluted EPS	(1.73)		(1.23)	(1.16)	(1.24)	(1.20)	(4.82)	(1.52)	(2.21)	(3.11)	(3.73)	(2.88)	3.48
Basic shares outstanding	6.6		8.5	8.5	8.6	8.6	8.6	8.6	8.6	8.7	8.7	8.8	8.8
Diluted shares outstanding	6.6		8.5	8.5	8.6	8.6	8.6	8.6	8.6	8.7	8.7	8.8	8.8

Source: Company reports and Canaccord Genuity estimates

RECOMMENDATION

We believe SCY-078 will become a very important novel second- or third-line treatment option for systemic fungal infections caused by candida and aspergilla. We think the drug will prove to have similar anti-infective potency as the gold standard echinocandins and likely better potency than the older generation, previously first-line treatment azoles. We also think the drug will prove to have acceptable safety and tolerability, with only mild GI adverse events and rare, transient cases of liver enzyme elevation.

We think the drug will prove to have little to no cross-resistance to echinocandins and azoles, making it an ideal second- or third-line agent, which may move into first-line as the prevalence of resistance grows.

We also think there may be more accurate diagnosis of systemic fungal infections in immunosuppressed patients that are susceptible to these infections (e.g., post-transplant and chemotherapy patients). We believe there is a significant amount of underdiagnosis of these infections, which should be reduced with improved diagnostic technology. Nevertheless, we still see a significant amount of empirical diagnosis-based treatment in the near to mid future.

We believe the Phase 2 trial that SCYNEXIS plans to initiate will be successful due to positive preclinical potency and Phase 1 safety precedent. We expect data from this trial in H2/15 which should support advancing the program into Ph3 in 2016 with approval in the 2018 time frame. As with most anti-infectives that have current treatment options, we believe the drug will reach peak sales in seven to nine years, slower than the five to seven years average for other types of common drugs. This is due to infectious disease specialists initially choosing to save the newest most potent anti-infectives for last line therapy in an effort to prevent emergence of resistance. Never the less, we model an estimated peak US market of \$337M.

COMPANY OVERVIEW

Scynexis is a clinical-development-stage biotechnology company discovering and developing novel anti-infectives addressing unmet therapeutic demand. The company's lead pipeline candidate is Phase 2a SCY-078 which is a novel oral and intravenous (IV) drug treatment for serious, and potentially fatal, invasive human fungal infections. SCY-078 has proven to be effective in vitro and in vivo animal studies across a broad range of *Candida* and *Aspergillus* fungal species. SCY-078's strength lies in its ability to be effective in drug-resistant strains due to its unique mechanism which inhibits polymer glucan synthesis, a critical component of fungal cell walls. *Candida* and *Aspergillus* infections account for approximately 85% of invasive American and European fungal infections. A Phase 2 study will begin in the second half of 2014 with an oral formulation of SCY-078 with an IV formulation entering enrollment in 2015. Data from the upcoming oral Phase 2 is due in Q4/15 to Q1/16.

DISEASE BACKGROUND

Infections are major causes of concern in the healthcare system. Opportunistic invasive fungal diseases (IFDs) are significant causes of morbidity and mortality in immunocompromised patients and are associated with an increase in healthcare costs.

Candida and *Aspergillus* species are responsible for approximately 85% of all invasive fungal infections in the US and Europe. Invasive fungal infections are on the rise due to increased use of immune-suppressing chemotherapies, transplant drugs, and in-dwelling catheters, among other common treatments. The increased use of broad spectrum antibiotics has also contributed to a heightened risk of fungal infection. Although *Candida* and *Aspergillus* are the most common fungal pathogens responsible for infection, diagnosis is quite difficult and often realized after the patient has become too ill to recover. Between 2000 and 2005, confirmed cases of invasive *Candida* infections rose by 52% in the US. *Aspergillus* infections nearly doubled in the US among patients receiving hematopoietic stem cell transplants (HSCT) between 2002 and 2005. Polyenes, azoles, and echinocandins are the primary treatment classes for IFDs, and although they have high levels of antifungal activity, resistance arises in all classes. Treatment can be further limited by toxicity, poor tolerability, and a narrow activity spectrum.

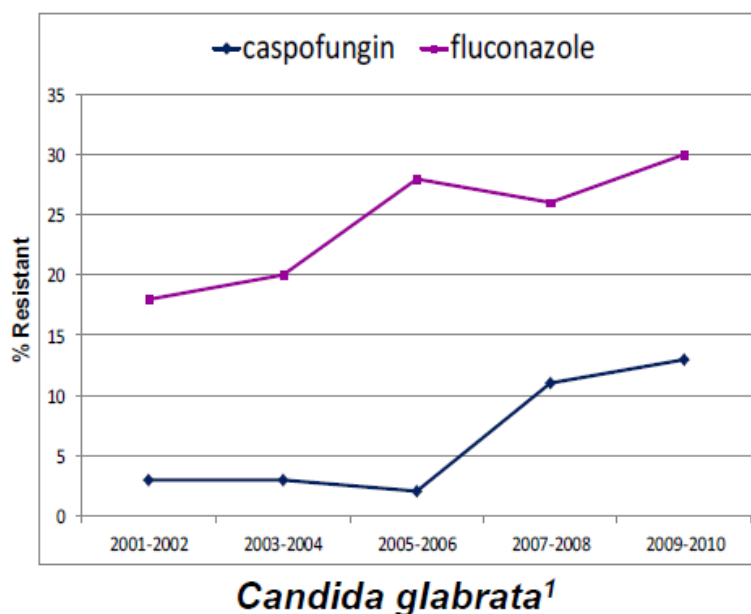
Diagnosis

Radiological findings, clinical course and response to antifungal treatment, microbiological cultures from respiratory tract samples or serologic and molecular findings can all be interpreted differently with respect to an individual case of possible or proven invasive aspergillosis. Isolation of the organism with histopathology or culture is the best way to confirm fungal infections, but this method is time consuming and can delay a timely diagnosis. Microscopy and several stain tests such as Gomori Methanamine-Silver (GMS), periodic acid-Schiff reagent (PAS), and calcofluor white tests can identify fungal cell walls, polysaccharide component of fungal cell walls, and fungi respectively. Gram staining is useful only for *Candida* and stains gram positive. Chest x-ray and CT scans of the chest, abdomen, and brain can help to discover characteristic features of disease.

Candida

Approximately 400,000 cases are reported worldwide annually. *Candida* are commensals of human mucotaneous surfaces and of the GI, respiratory, and female genital tracts. They are the fourth most common organism recovered from blood culture isolates in US hospitals (8%-10% of all nosocomial bloodstream infections). Candidiasis define a range of infections that range from superficial (oral thrush, vaginitis) to systemic and potentially life-threatening diseases (often referred to as candidemia or invasive candidiasis, which are usually confined to severely immunocompromised patients such as those with cancer, transplants, AIDS, and non-trauma emergency surgery). Invasive candidiasis is associated with an attributable mortality rate of 20-60%. When organisms enter the blood stream, they can invade deep tissues and organs such as the brain, heart and kidneys, thereby causing extremely dangerous physical ramifications. *C. albicans*, *C. glabrata*, *C. tropicalis*, and *C. parapsilosis* are the most commonly recovered species (in order of prevalence). Invasive candidosis, particularly candidemia, is the most frequent systemic fungal infection in patients undergoing complex abdominal surgery as well as in patients receiving total parenteral nutrition, neutropenic patients with malignancies, burn patients, patient receiving long-term treatment of prednisone (20 mg/day) and low weight pre-term infants.

The increased use of antifungals (in the case of candidemias, caspofungin and fluconazole) has led to an increase in resistant strains of *Candida*. *Candida glabrata* *Candida albicans* are common antifungal resistant strains. The figure below shows the increase in *Candida glabrata* resistant strains since 2001.

Figure 4: Increase in resistance to caspofungin and fluconazole

Source: Company presentation

Candidemia occurs in 5-10 patients per 10,000 admitted to a primary care hospital in the USA. The mortality rate in patients with candidemia is 40-75%. One retrospective study of patients with candidemia found the number of days that passed from notification of the first positive culture for yeast to the initiation of fluconazole correlated highly with mortality rates as follows:

- Day 0: 15% mortality
- Day 1: 24% mortality
- Day 2: 37% mortality
- Day 3: 41% mortality

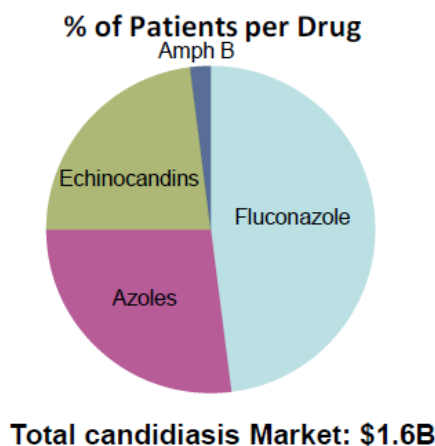
Risk factors associated with an increased mortality rate are patients over 64 years old, non-removal of a central venous catheter (if present), poor performance status, hypotension, and a *Candida* spp. other than *C. parapsilosis*.

The Infectious Diseases Society of America (IDSA) recommends fluconazole or echinocandin as a first-line of therapy for non-neutropaenic patients with candida. Neutropaenic patients should be treated with echinocandins until the candida species is determined. The figure below shows the recommended treatment for patients at various stages of the disease and diagnosis. European recommendations are pushing azoles to second-line treatment as azole resistance is an even bigger problem in EU territories.

Figure 5: IDSA treatment recommendation

Management according to clinical condition and microbiological documentation	IDSA treatment recommendation
Initial therapy	Fluconazole, Echinocandin
Moderately severe-severely ill	Echinocandin
Recent azole exposure	Echinocandin
Less critically ill and no recent azole exposure	Fluconazole, Echinocandin
<i>C. glabrata</i>	Echinocandin
<i>C. parapsilosis</i>	Floconazole
Step-down therapy for clinically stable and isolate susceptible to fluconazole	Echinocandin to fluconazole, D-AmB to L-AmB
Duration of therapy	2 weeks after clearance of <i>Candida</i> bloodstream infections and resolution of symptoms

Source: Adapted from Virulence 5:1, 161-169; January 1, 2014

Figure 6: Candidiasis Market

Source: Company presentation

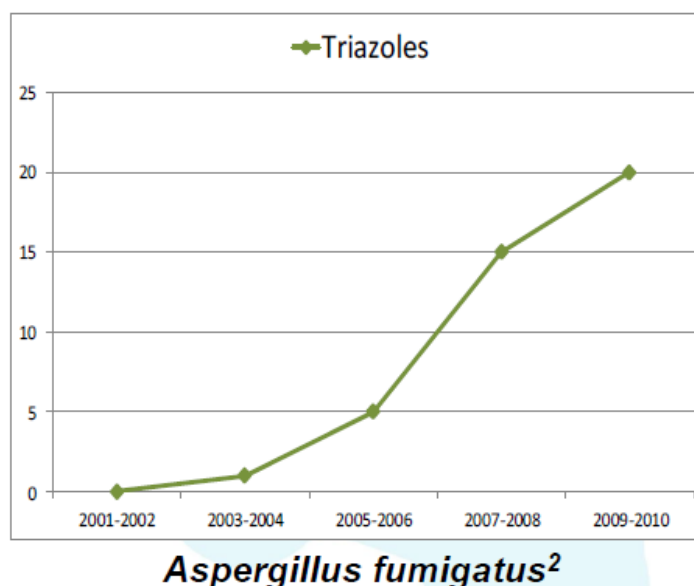
Investigators have looked into immunotherapies as potential treatment for candida. Several studies have shown a correlation between IFN- γ levels and an increased risk for systemic candidiasis. Immunotherapies could be a viable treatment for candidemia if more data on their safety and efficacy is shown.

Aspergillus

Invasive aspergillosis has become one of the most well-known opportunistic infections in transplant units worldwide and generates ~\$600M in annual hospitalization costs in the US. The incidence of invasive aspergillosis continues to increase in proportion to the rise in the at-risk population, and this rise has not been met by an increase in the number of effective antifungal agents to treat the infection. Approximately 150,000 cases are diagnosed worldwide annually. *Aspergillus* is the most pathogenic mold (a filamentous fungi composed of hyphae) and the most common to cause invasive disease. They grow as

molds in the environment and as hyphal forms in the tissue. Invasive *Aspergillus* appears most frequently in the respiratory tracts of those with underlying chronic pulmonary disease. The majority of invasive *Aspergillus* infections have a fatal outcome. Mortality rates are as high as 90% (found in patients with CNS involvement or a disseminated invasive aspergillosis), and 61% of patients with invasive aspergillosis have an underlying hematologic disease or have undergone bone marrow transplant (BMT). Risk factors are prolonged or repeated episodes of profound neutropenia, solid organ or HSCT, grade III or IV graft vs host disease, and steroid therapy. The broad range of incidence among patients with different underlying conditions is due to the difficulties in diagnosing aspergillosis prior to death and significant differences in the local epidemiology of the infection. Like *Candida*, *Aspergillus* strains (*Aspergillus fumigatus* is the most common triazole resistant strain) have also generated resistance to Triazole treatment.

Figure 7: *Aspergillus fumigatus*



Source: Company presentation

The severity of illness depends on the immune status of the patient as well as the intensity of exposure. Inhalation leads to initial infection of the lungs, which can result in it spreading to other sites in the body, but most acute infections go unrecognized with asymptomatic or mild illness.

The body's natural defense mechanisms are needed to prevent and contain fungal disease. The cell-mediated arm of the immune system is important in producing inflammation and in initiating the cytokine and chemokine production for the recruitment of macrophages and neutrophils to combat infection. The hallmark of tissue response is the development of caseating or noncaseating granulomas mixtures of mononuclear phagocytes and lymphocytes, mostly T cells, to contain fungal growth.

Immunocompromised patients with HIV/AIDS and anyone treated with prolonged corticosteroids are at a higher risk to contract *Aspergillus*. The figure below shows

underlying conditions or procedures that significantly increase an individual's risk of acquiring invasive *Aspergillus* infection.

Figure 8: Risk factors for invasive *Aspergillus* infection

Incidence of invasive <i>Aspergillus</i> infections (after)	
Underlying condition	Incidence of invasive aspergillosis (%)
Allogenic BMT/PBSCT	≤9
Solid organ transplantation	≤30
Acute leukemia	≤24
Severe combined immunodeficiency	≤4
Burns	≤7
Solid tumor or lymphoma	≤3
Autologous PBSCT	1
Autoimmune disease	1
Chronic granulomatous disease	25-40

Source: Adapted from *Mycoses*, 47, 263-276

TREATMENT

The success of systemic antifungal treatment is highly dependent upon how early in the course of infection the treatment was initiated. Physicians may be reluctant to treat patients because of the toxicity and costs of treatment, and this must be weighed against the high fatality rate of patients who are not given antifungal treatment until their disease has been unequivocally proven (which can be costly and time consuming). Early identification and pre-emptive treatment can reduce fatality rate from approximately 90% to 50% of aspergillosis patients. Confirmed cases of *Candida* blood infections only account for 25%-33% of *Candida* treatments. The difficulty of diagnosis often warrants treatment in at-risk patients, and the initiation of therapy within the first twelve hours following suspicion of fungal infection has been shown to reduce the risk of death by threefold.

A gamut of antifungal agents is available for the treatment of invasive candidosis and aspergillosis. In 2012, total antifungal Rx sales were ~\$6B (including topical; see Figure 9). Company guidance suggests a ~\$3.6B addressable market. Because of the difficulty and time constraints in diagnosing antifungals, prophylaxis, empiric, and pre-emptive treatment account for 66%-75% of total systemic antifungal use.

1. **Polyenes** disrupt fungal cell membranes and are used to treat the broadest spectrum of fungi compared with the treatment spectrum of other antifungals. They bind to ergosterol, thereby disrupting the membrane and causing cell death. **Amphotericin B deoxycholate (D-AmB)** was considered the drug of choice for the primary treatment of aspergillosis. It was licensed more than 50 years ago based on vague data on combating pathogenic fungi in humans. Recent data, however, suggests a response rate (partial or complete response) of less than 35% in D-AmB patients. This is, however, difficult to determine due to a high percentage of patients that cannot tolerate the dose of D-AmB that would be needed to show clinical efficacy. Infusion-

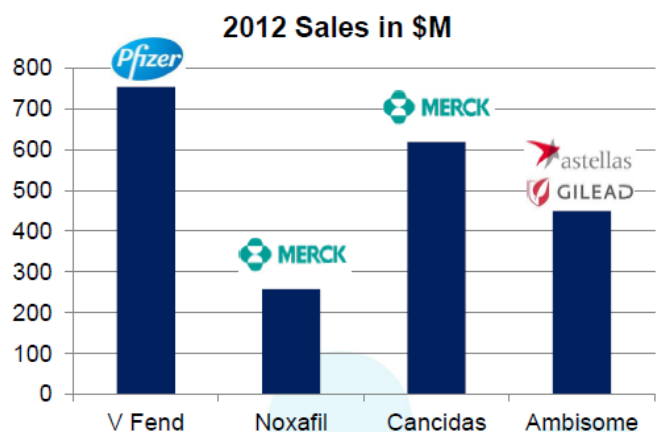
related adverse events are usually fever, chills, dyspnea/skin reactions, and nephrotoxicity. Lipid formulations do have reduced toxicities but are also more expensive. They are indicated for patients with systemic mycoses who are intolerant of or refractory to D-AmB. The available lipid formulations (L-AmB) are: Amphocil or amphotec, Abelcet, AmBisome. They allow for higher doses of AMB, and higher doses are also required for equivalent antifungal efficacy because amphotecin must be released from the synthetic phospholipids when near ergosterol, thereby allowing for the delivery of enough AMB to the infection site. This, however, doesn't contribute to the adverse event profile because L-AmBs preferentially distribute to the endothelial system tissues and functionally spare the kidney. Therefore, smaller quantities of L-AmB are released from the lipid carrier in the kidney because the phospholipids have a greater affinity for AMB than cholesterol in the renal epithelial membranes. Infusion-related adverse events (fever, chills, rigor) are less frequent with lipid conjugated AMB compared with D-AmB.

2. **Azoles** block the formation of the fungal cell membrane by inhibiting ergosterol synthesis. They are generally active against *Candida*, and certain azoles have a spectrum of activity against *Aspergillus*. The use of azoles has contributed to azole-resistant infections such as *Candida glabrata* and *Candida krusei*. Hospitals performing medically intensive procedures such as transplantation have patients with rates of a reduced azole susceptibility of 15-20%. Cross-resistance has also developed among azoles (once one azole has been tried another azole may not be effective). Broad use of azoles in *Aspergillus* species contributed to their resistance, and a 2010 study found that about 50% of *Aspergillus fumigatus* species (which account for most of the *aspergillus* fungal infections in the US) were resistant. They are often used for prevention and in unconfirmed cases and are available in oral, IV, and topical formulations. The current azoles available are fluconazole (Diflucan), itraconazole (Sporanox), and ketoconazole (Nizoral). Second generation azoles, voriconazole (Vfend) and posaconazole (Noxafil) are synthetic triazole derivatives of fluconazole. Most azoles are well tolerated, and side effects usually include GI upset and elevated liver enzymes. Certain azoles (itraconazole and vorticonazole) are limited in use because of significant drug-drug interactions. Nonetheless, annual sales of azoles as a class exceeded \$2.1B in 2012. Voriconazole, the leading azole, generated \$754M in revenues in 2012.
3. **Echinocandins** block the biosynthesis of fungal cell walls by inhibiting a glucan synthase enzyme, an enzyme that is not found in human cells. They are the newest class of antifungal agents, are administered by IV, and include caspofungin (Cancidas), micafungin (Mycamine) and anidulofungin (Eraxis). The echinocandins have antifungal activity even against azole-resistant strains and have shown superior efficacy against D-AmB. Echinocandins have a mild tolerability profile, and the most common AEs are headache, nausea, vomiting, flushing and infusion-related pruritus, erythema, and pain. About 10% of patients develop elevations of liver enzymes. Resistance against echinocandins is beginning to appear in *Candida glabrata* at an incidence rate exceeding 10%. The majority of *Candida* strains that are resistant to echinocandins are also resistant to azoles. Sales of echinocandins were approximately \$1.1B in 2012, with Caspofungin, the lead echinocandin, generating \$619M.
4. **Pyrimidines** used for fungal infections are flucytosine (5-fluorocytosine), which inhibits DNA and protein synthesis. It works against *Candida* spp. and some molds.

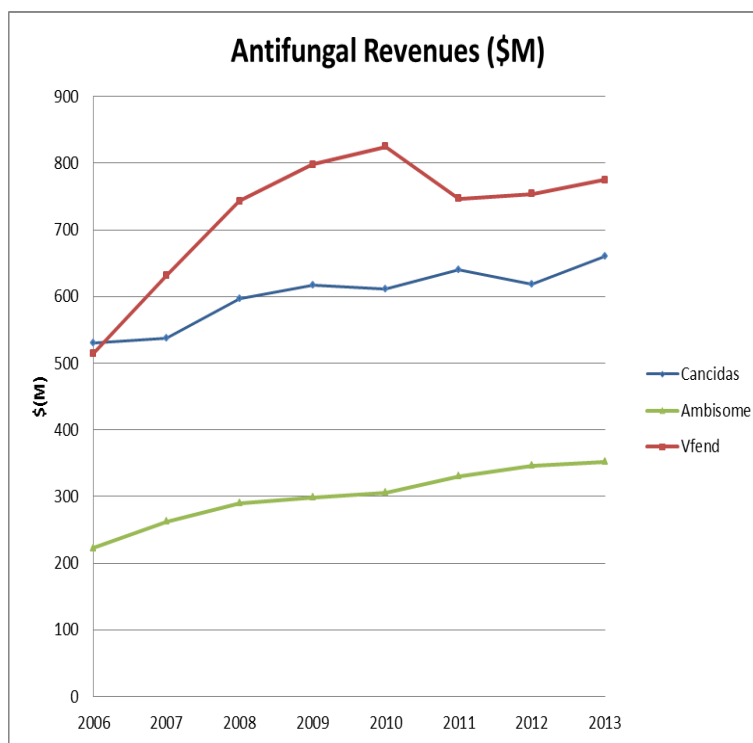
Typical AEs include rash, nausea, vomiting, diarrhea, liver dysfunction, and bone marrow suppression. Flucytosine is typically used in combination with D-AmB because of the emergence of resistance, and it is typically only used for select life-threatening and disseminated fungal infections.

5. **Combination therapy** has shown potential in different mechanisms of action. Triazoles and echinocandins with amphotericin B, for example, have been used successfully to treat invasive aspergillosis. More in-depth and randomized trials need to be done to accurately establish usefulness, and the routine use of antifungal combinations as a primary therapy is not currently recommended.

Figure 9: Sales of leading antifungal therapies



Source: Company presentation

Figure 10: Increase in antifungal revenues since 2006

Source: Canaccord Genuity and company earnings reports

SCY-078

Mechanism of action

SCY-078 is a potent inhibitor of the synthesis of fungal cell wall polymer glucan. This glucan is a critical component of *Candida* and *Aspergillus* proliferation, and inhibition of its synthesis is a clinically proven antifungal mechanism that has been established by other antifungal agents such as the echinocandin class. Given that SCY-078 was active against the majority of echinocandin-resistant strains indicates the SCY-078 mechanism is sufficiently different from the echinocandin mechanism.

The Fungal Cell Wall

The diagram illustrates the layers of the fungal cell wall. From the outside in, the layers are:

- Chitin**: The outermost layer, composed of long, parallel chains of N-acetylglucosamine (NAG) units.
- β -glucans**: A layer of branched polysaccharides located beneath the chitin.
- Cell membrane**: The innermost layer, composed of a phospholipid bilayer.

 Embedded within the β -glucan layer is the enzyme **Glucan Synthase**, which is responsible for synthesizing and inserting β -glucan into the cell wall.

Drug targets are indicated by arrows:

- Amphotericin** and **Azoles** target the **Cell membrane**.
- Echinocandins** and **Enfumafungins** target **Glucan Synthase**.

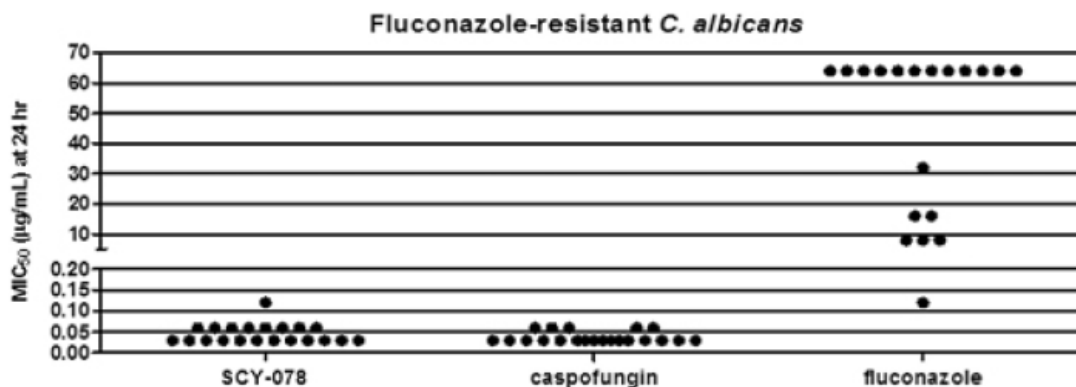
Figure 2 consists of two scatter plots. The left plot shows the Minimum Inhibitory Concentration (MIC) in µg/mL at 24 hours for five *Candida* species. The y-axis ranges from 0.0 to 1.2. The x-axis lists *C. albicans*, *C. glabrata*, *C. krusei*, *C. parapsilosis*, and *C. tropicalis*. Data points are shown for SCY-078 (open circles) and caspofungin (filled squares). For *C. albicans*, MICs are mostly 0.05-0.1 µg/mL. For *C. glabrata*, MICs are 0.05-0.2 µg/mL. For *C. krusei*, SCY-078 MICs are 0.5 µg/mL and caspofungin MICs are 1.0 µg/mL. For *C. parapsilosis*, SCY-078 MICs are 0.05-0.25 µg/mL and caspofungin MICs are 0.5 µg/mL. For *C. tropicalis*, SCY-078 MICs are 0.05-0.25 µg/mL and caspofungin MICs are 0.05-0.1 µg/mL.

The right plot shows the Minimum Effective Concentration (MEC) in µg/mL at 24 hours for four *Aspergillus* species. The y-axis ranges from 0.0 to 0.6. The x-axis lists *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus*. Data points are shown for SCY-078 (open circles) and caspofungin (filled squares). For *A. fumigatus*, MECs are 0.0-0.15 µg/mL. For *A. flavus*, MECs are 0.0-0.15 µg/mL. For *A. niger*, MECs are 0.0-0.1 µg/mL. For *A. terreus*, MECs are 0.0-0.15 µg/mL.

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ineffective. SCY-078 demonstrated activity against all azole-resistant *Candida* strains with activity similar to that observed against wild-type strains. The figure below illustrates the in vitro activity of SCY-078 and its comparability to the leading treatment, caspofungin, and against *Candida albicans* resistant to fluconazole. SCY-078 also demonstrated activity against all azole-resistant *Aspergillus* strains with MEC50 values comparable to those observed against wild-type strains.

Figure 13: SCY-078 in vitro activity against *C. Albicans*

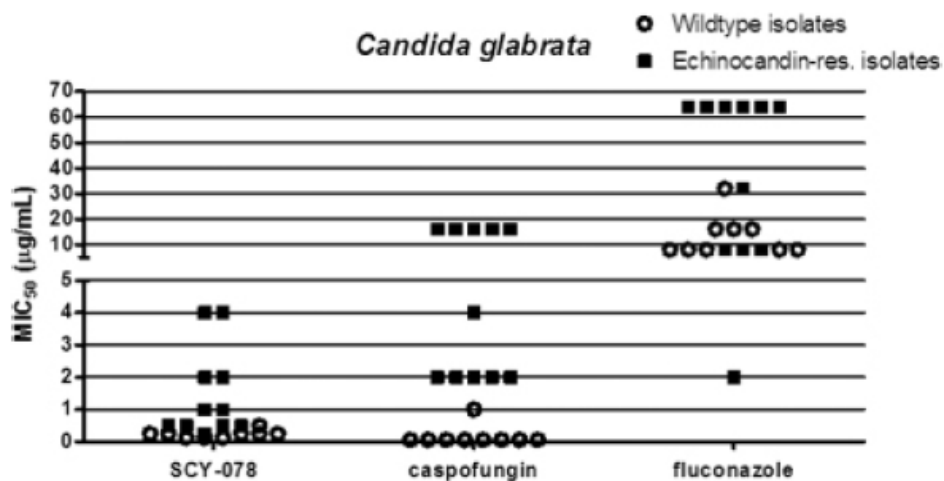


Source: Company data

SCY-078's in vivo activity against a majority of echinocandin-resistant Candida species

Like the spread of azole resistance, echinocandin resistance is also spreading especially amongst azole-resistant species like *Candida glabrata*. The figure below illustrates SCY-078's in vitro activity against *Candida glabrata* strains that are echinocandin-resistant. Other tests of echinocandin-resistant strains of other *Candida* species yielded similar results, indicating SCY-078 may offer a therapeutic option against strains that are multi-drug resistant such as those which have emerged in *Candida glabrata*.

Figure 14: SCY-078's in vitro activity against echinocandin-resistant *Candida glabrata* strains



Source: Company data

Safety parameters to monitor SCY-078 in clinical studies indicated by nonclinical toxicology studies

SCY-078's preclinical safety has been evaluated in nine exploratory and two Good Laboratory Practice (GLP) studies in rats, dogs, rabbits and nonhuman primates, with the longest oral dosing duration of 28 days. At the highest tested doses, very slight to moderate toxicities were observed in two animal species at exposures that were seven-fold the originally targeted efficacious exposure.

Pharmacology studies indicated there were no clinically significant effects of SCY-078 on markers of cardiovascular, respiratory, or CNS function. SCY-078 also demonstrated potent in vivo antifungal activity in *Candida*- and *Aspergillus*-infected mouse models, which bolsters support of SCY-078's clinical efficacy profile.

Clinical experience with SCY-078: Phase 2 safety likely to build off clean Phase 1

Four of seven studies evaluated one oral dose while three studies evaluated multiple oral doses of SCY-078, with the drug consistently showing sufficient safety and tolerability data in Phase 1 studies to support progression into Phase 2 studies. Over 100 healthy test subjects were administered one dose of SCY-078 in seven Phase I studies, with the drug showing good tolerability at initial oral doses of up to 1800mg in one day and doses up to 800mg per day for 28 sequential days. Reported adverse events (AEs) have been generally transient and mild to moderate in intensity, with gastrointestinal (GI) leading reported AEs. GI AEs were not considered serious, and only one subject discontinued drug dosing due to GI AEs. Six subjects who received 800mg of SCY-078 for 28 days in another study underwent pre- and end-of-treatment gastric endoscopy including biopsy which revealed no degeneration of the stomach lining and no other significant clinical finding. Additionally, none of the 66 subjects in the four Phase I studies receiving SCY-078 that were being monitored for gastrin levels deviated from the normal range. One test subject discontinued SCY-078 after experiencing meaningful liver function test increases after the initial dose the investigator deemed drug-related. A counter to the severity of this AE lies in pre-dose data of the subject where liver injury ALT and AST markers were already increasing prior to the subject receiving SCY-078. This subject exhibited ALT levels that increased beyond the upper limit of what is considered normal with other markers of liver injury remaining in the normal range. Both liver injury markers returned to normal post-dosing. One other serious AE was reported with one subject being diagnosed with a metastatic carcinoid tumor after one SCY-078 dose; however, this AE was not deemed related to SCY-078.

Pharmacokinetics in humans

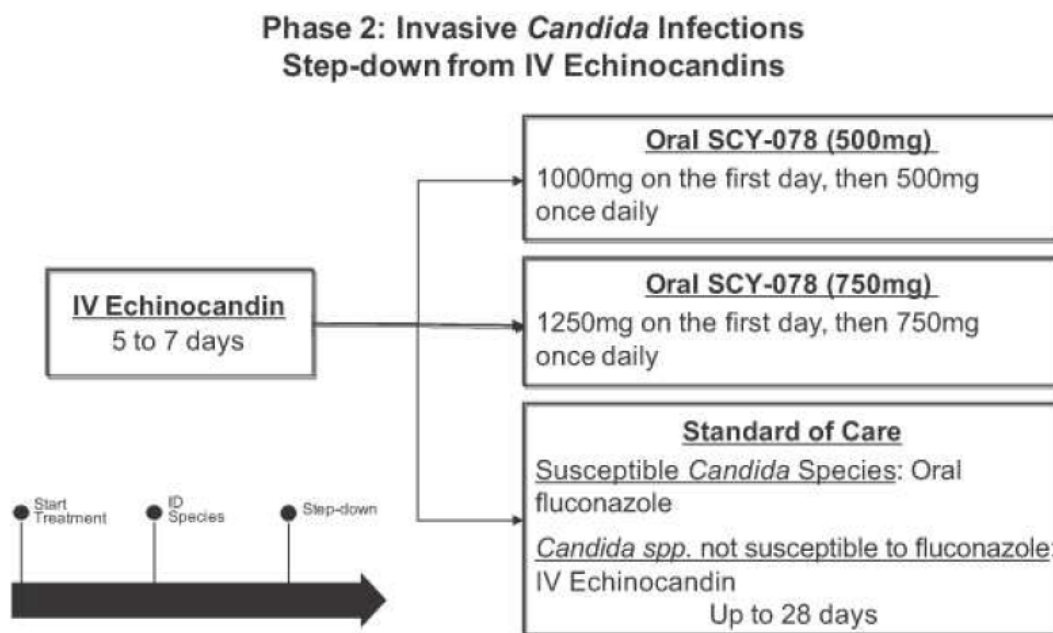
SCY-078 has a half-life of ~20 hours, which is supportive of once daily dosing. Additionally, load dosing on the initial day should result in therapeutic concentrations being achievable initially. SCY-078 exhibited no major differences in the pharmacokinetics (PK) or safety in either healthy elderly subjects or younger adult subjects. Results of common drug metabolizing enzymes indicated that a dose reduction of SCY-078 would be required with moderate CYP3A inhibitors and co-administration with strong inhibitors would not be a recommended treatment option. Given that drug interaction studies of SCY-078 with pantoprazole indicated pantoprazole was ~25% lower than SCY-078, the initial hypothesis that exposures of SCY-078 with or without a proton pump inhibitor were generally similar.

Efficacious SCY-078 drug levels in mouse models indicate that the levels achieved in human Phase 1 clinical trials are a reasonable predictor of efficacy in patients that are infected.

Upcoming Phase 2 trials

SCYNEXIS will pursue SCY-078 as an oral step-down agent proceeding echinocandin IV treatment in patients with invasive Candida infections. The open label study will enroll approximately 120 patients and will be a three arm study that compares step-down oral therapy with two doses of SCY-078 to the current standard of care. Infected patients will begin with echinocandin IV therapy for five to seven days and based on clinical and microbiological response they will be switched to a randomized therapy. The figure below highlights the treatment pathways: oral SCY-078 500mg, oral SCY-078 750mg, and standard of care. The treatment will last for at least 14 days after the first negative Candida culture.

Figure 15: Phase 2 step-down from IV echinocandins



Source: Company data

SCYNEXIS is also pursuing an IV formulation of SCY-078 that should be available for clinical studies in the first half of 2015. This study of SCY-078 will evaluate the efficacy and safety of the drug in patients that undergo both oral and IV formulations. The study will be focused on indications with an unmet need and has the potential to show differentiation from available therapies for invasive candidiasis.

SCYNEXIS will also pursue an initial indication for SCY-078 as an oral/IV drug for treating invasive infections of the *Candida* strain in patients who have previously been treated with azoles and/or echinocandins.

SCYX PIPELINE

SCY-635

SCY-635 is the company's first clinical candidate derived from its Cyclophilin Inhibitor Platform. It is an orally bioavailable agent for the treatment of hepatitis C virus (HCV) that reverses the HCV-induced immunosuppression of innate immune responses in HCV infected hepatocytes and in non-infected blood cells taken from HCV infected subjects. Phase 1b proof of concept studies showed successful treatment of patients chronically infected with genotype 1 HCV. A Phase 2a study was recently performed in a difficult-to-treat population, and the drug modified patients' immune responses within 28 days.

SCY-641

SCY-641 is being developed as an eye-drop treatment for dry-eye disease. It is a novel cyclosporine derivative that inhibits the production of inflammatory cytokines and has greater water solubility and is better tolerated than the currently available cyclosporine A treatment paradigm.

SCY-7158

SCY-7158 is an oxaborole that has been shown as safe and efficacious in rodent models of Human African Trypanosomiasis (HAT) in preclinical studies. Its first studies in infected patients in Africa are scheduled to begin in 2014.

Figure 16: SCYX pipeline

Program	Disease	Stage
SCY-635	HCV/HBV	Ph2B
SCY-078	Invasive Fungal Infections	Ph2
SCYX-7158	Sleeping Sickness	Ph1
SCY-641	Dry Eye	pre-clinical
Antifungals	Invasive Fungal Infections	pre-clinical
HBV	HBV	pre-clinical
Animal Health		
SCY-641	Dry Eye	Efficacy

Source: Canaccord Genuity and company website

INTELLECTUAL PROPERTY

Figure 17: SCYX intellectual property profile

Compound	Patent Number	Type	Expiration Year
SCY-078	U.S. 8,188,085	Composition of Matter	2030
	U.S. 8,674,087	Composition of Matter	2030
SCY-635	U.S. 20,100,173,837	Method of Use	2030
	U.S. 20,100,227,801	Composition of Matter	2030
SCY-641	U.S. 6,583,265	Composition of Matter	2019
	U.S. 8,188,052	Method of Use	2029
	U.S. 8,551,952	Method of Use	2027
	U.S. 8,536,114	Composition of Matter/Method of Use	2028

Source: Company reports and U.S. Patent Office

MANAGEMENT

Figure 18: SCYX management team

Name	Title	Work History	Joined Scynexis In:
Yves J. Ribeill, Ph.D.	President and CEO	Aventis Rhône-Poulenc Rorer	1999
Vivian W. Doelling, Ph.D.	Vice President of Animal Health	Integrated Laboratory Systems Embrex, Inc. American Cyanamid Company	2013
Michael Garrett	Vice President of Corporate and Strategic Development	Pharmavent Partners BTG plc.	2006
Amanda S. Manusco	Chief of Staff	Rhône- Poulenc Agricultural Company	2012
Charles F. Osbourne, Jr.	CFO	Nobex Corporation International Murex Technologies Co.	2003
Eileen C. Pruette	General Counsel	bioMerieux S.A. Valeant Pharmaceuticals Sony Ericsson Telefonaktiebolaget L. M. Ericsson GlaxoSmithKline plc. Moore & Van Allen PLLC	2012
Carole Sable, MD	Chief Medical Officer	Merck & Co., Inc Novexel S.A. Novexel Inc.	2014

Source: Company reports

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(as of 31 March 2014)

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	#	%	%
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Speculative Buy	43	4.4%	55.8%
Hold	317	32.1%	13.2%
Sell	45	4.6%	4.4%
	988*	100.0%	

*Total includes stocks that are Under Review

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Canaccord Genuity Research Disclosures as of 29 May 2014

Company	Disclosure
SCYNEXIS	1A, 2, 3, 5, 7

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