

# **RBC Capital Markets**

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# **SCYNEXIS Inc.**

# Phase II study started; data could prove interesting in multiple ways

**Our view:** SCY-078 Phase II in invasive candidiasis has started, could read out 2H:15, and has the potential to generate meaningful data given the design. SCYX remains attractive because SCY-078 is a novel mechanism of action, targets life threatening fungal infections resistant to current drugs, is hospital focused, could go into pivotal Phase II/ III in 2016, is 100% owned, and has IP into 2030.

### **Key points:**

- 3Q:14 results vs. expectations. Revenues were in-line and expenses higher driving an EPS of (\$0.45) vs. consensus at (\$0.51). Sep. ending cash was ~\$34M.
- 2014 guidance vs. consensus. No formal guidance is given.
- Changes to our estimates. We modestly raised our expense estimates going forward.

### Key updates from the conference call:

- SCY-078 Phase II started with oral formulation; data important and in 2H:15. Patients have invasive candidiasis and will receive intravenous Mycamine (micafungin), an echinocandin, for 5-7 days, followed by either oral fluconazole, an azole, or oral SCY-078 (500 mg or 750 mg), an enfumafungin derivative that inhibits glucan synthase but works independently of how echinocandins work, for at least 14 days. Patient susceptibility would be evaluated prior to getting fluconazole so there is a chance some could continue on i.v. echinocandin. This in turn is another value proposition for SCY-078, as a step-down to i.v. echinocandins (since echinocandins are not available as orals and as it could prove an alternative for those who cannot receive oral fluconazole. Results are likely by YE:15 but could be sooner depending on enrollment timelines. The objective is safety, tolerability for a dose that demonstrates a benefit and not necessarily direct differentiation vs. fluconazole, which is unlikely at this stage as most patients would have responded to micafungin.
- SCY-078 Phase I i.v formulation on track for 2015 start. We estimate Phase I could begin in 1H:15 and readout in 2015 as well. The key here is the ability to start patients on i.v. SCY-078 and transition them to oral SCY-078. The oral has QIDP designation so we expect the same for the i.v. form. Once an i.v. is in place future trials could compare vs. micafungin or in resistant or refractory disease.
- Business development activities likely to continue. SCYX recently outlicensed SCY-635 to Waterstone Pharmaceuticals as a candidate for treating HCV/ HBV infections (see note dated Nov. 3rd for details). Since the focus is on SCY-078 letting another party advance this and potentially other pipeline assets provides upside optionality at no cost to SCYX.

### **Upcoming news flow:**

- SCY-078 Phase II oral data in 3Q/4Q:15.
- SCY-078 Phase I i.v. data in 2015.

# Outperform

**Speculative Risk** 

NASDAQ: SCYX; USD 9.49

### **Price Target USD 17.00**

WHAT'S INSIDE	
☐ Rating/Risk Change	☐ Price Target Change
☐ In-Depth Report	☑ Est. Change
Preview	☐ News Analysis

### Scenario Analysis\*

4	Downside Scenario	Current Price	Price Target	Upside Scenario	
	4.00	9.49	17.00	34.00	
	<b>↓</b> 58%		<b>†</b> 79%	<b>†</b> 258%	

\*Implied Total Returns

#### **Key Statistics**

Shares O/S (MM):	9.7	Market Cap (MM):	92
Dividend:	0.00	Yield:	0.0%
		Avg. Daily Volume:	19.975

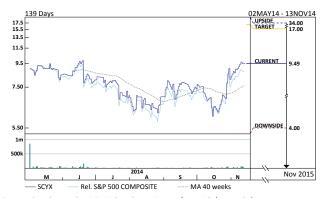
### **RBC Estimates**

FY Dec	2013A	2014E	2015E	2016E
Revenue	16.9	18.2	18.0	18.1
Prev.		18.3		
EPS, Ops Diluted	(6.84)	(3.88)	(2.47)	(2.02)
Prev.		(3.83)	(2.23)	(2.01)
P/E	NM	NM	NM	NM
Revenue	Q1	Q2	Q3	Q4
2014	4.7A	4.6A	4.4A	4.5E
Prev.			4.5E	
2015	4.5E	4.5E	4.5E	4.5E
EPS, Ops Diluted				
2014	(3.65)A	(0.98)A	(0.45)A	(0.58)E
Prev.			(0.42)E	
2015	(0.56)E	(0.59)E	(0.62)E	(0.70)E
Prev.	(0.50)E	(0.53)E	(0.56)E	(0.64)E
FPS One Diluted: Basi	c shares user	when FPS	are negative	

EPS, Ops Diluted: Basic shares used when EPS are negative All values in USD unless otherwise noted.

### **Target/Upside/Downside Scenarios**

### Exhibit 1: SCYNEXIS Inc.



Source: Bloomberg and RBC Capital Markets estimates for Upside/Downside/Target

### Target price/base case

We value SCYX at \$17 per share, which includes US and ROW sales of SCY-078. We assign a probability of success of 65% and a value of ~\$6 per share to the US and \$11 per share to the ROW opportunity. We assume a US launch in 2019 and an ROW launch in 2020. Currently, we assume that SCYX will sell SCY-078 in the US and a partner will commercialize these compounds outside the US. We forecast peak SCY-078 sales of \$300-400MM in the US and \$1.0-1.4B in the ROW.

### **Upside scenario**

Our upside scenario includes  $^{16}$  per share in value for the US opportunity and  $^{18}$  per share in value for the ROW opportunity. We forecast peak SCY-078 sales of  $^{600-700MM}$  in the US and  $^{1.7B-92B}$  in the ROW. We assign SCY-078 a 60% probability of success, a discount rate of 15%, and use a terminal growth rate of -50%.

### **Downside scenario**

Our downside scenario assumes that SCY-078 may not be successful clinically or commercially either because efficacy against resistant organisms was not borne out or it was not long lasting or an unexpected adverse event was seen. Under such a scenario shares would trade at roughly cash per share which is currently ~\$4 (prev. \$5).

### **Investment summary**

Scynexis' (SCYX) SCY-078 treats systemic fungal infections via a new mechanism of action that attacks the fungal cell wall, a validated target. These infections are serious, have high rates of mortality, and rates of resistance to current drugs are rising. All currently available drugs have limitations, which allow SCY-078 to generate an attractive value proposition. The worldwide market for systemic anti-fungals is nearly \$4B. Roughly 600,000 patients are identified with invasive fungal infections and an even higher number is treated. Phase I studies are completed for the oral version and in vitro and in vivo data shows activity in organisms both susceptible and resistant to currently approved drugs. Next up is a Phase II for the oral and a Phase I for the intravenous form with data in 2015. A Phase II/III study in resistant patients could start in 2016 and potentially provide a more rapid path to the market. SCYX essentially owns all rights to SCY-078, which is patent protected through 2030, as well as to its anti-fungal pipeline. This leaves SCYX free to commercialize the products itself, partner on a global or regional basis, and/or sell the company.

### **Potential catalysts for SCYX shares**

- Phase II data for oral SCY-078 in 2015. Important catalyst as this will be the first time SCY-078 will be used in human patients.
- Phase I data for intravenous SCY-078 in 2015. Important as an intravenous does not yet exist and is needed to maximize the value of SCY-078 franchise.
- Phase II/III trial design in 2015/2016. A sign off from the FDA could determine the pace and potential path to the market.
- Phase II/III trial start in 2016 and data by YE:17/ early 2018.
   A Phase II/III study in drug resistant patients could be the first proof that SCY-078 can achieve in patients what it is designed to do and has shown in in vitro and in vivo models.
- Business development activities in 2014/2015. Non-core pipeline assets and even SCY-078 could be partnered opportunistically raising non-dilutive capital.

### Risks to our investment thesis

- Clinical studies for oral and intravenous SCY-078 could fail.
   Expectations are based on pre-clinical and Phase I data and human studies could show a lack of efficacy or emergence of resistance.
- Merck returned rights for SCY-078 back to SCYX. This raises
  the question of whether MRK saw anything in SCY-078's
  clinical or commercial profile that was lacking.
- Sales ramp of SCY-078 could lag expectations unless rates of resistance continue to rise.
- SCYX could fail to find a partner outside the US for SCY-078.
- Timelines are rapid and any delays could disappoint investors.

Exhibit 2: 3Q:14 Actuals vs. RBC estimates

(in MM; except per share)	3Q:14A	Est.	Var.
Revenue:			
SCY-078			
Other Revenue	4.4	4.5	(0.1)
Total Revenue	4.4	4.5	(0.1)
Operating expenses:			
Cost of Other Revenue	3.7	4.1	(0.4)
R&D	2.5	2.8	(0.3)
SG&A	2.0	1.3	0.8
Other			
Total Expenses	8.2	8.1	0.1
Operating Expense (income)	(3.8)	(3.6)	(0.3)
Other:			
Amortization of deferred financing cost and debt discount			
Interest expense for beneficial conversion feature			
Interest expense-related party			
Interest expense			
Derivative fair value adjustment			
Other income		(0.1)	0.1
Income before Tax	(3.8)	(3.6)	(0.2)
Taxes			
Net income (loss)	(3.8)	(3.6)	(0.2)
EPS, Basic (GAAP)	(\$0.45)	(\$0.42)	(\$0.03)
EPS, Diluted (GAAP)	(\$0.41)	(\$0.39)	(\$0.02)
Shares outstanding, Basic	8.5	8.5	(0.0)
Shares outstanding, Diluted	9.3	9.3	(0.0)

Source: Company reports and RBC Capital Market estimates

Exhibit 3: News flow

Timing	Expected News Flow	Program
Late 2014/ early 2015	Request QIDP designation for i.v. SCY-078	SCY-078
2014/2015	Potential pipeline related business development	
1H:15	Initiate Phase I study with i.v. SCY-078	SCY-078
Mid/ 2H:15	Phase I intravenous SCY-078 results	SCY-078
2015	Phase II update from oral SCY-078 step down study	SCY-078
2H:15/ 1Q:16	Phase II results from oral SCY-078 step down study	SCY-078
2016	Initiate Phase II/III i.v. to oral SCY-078 in relapsed/ refractory patients	SCY-078
YE:2016/ early 2017	Initiate Phase III study for i.v. to oral SCY-078 in 1st line patients	SCY-078
Late 2017/ early 2018	Phase II/III i.v. to oral data	SCY-078
2018	Potential NDA for SCY-078	SCY-078
YE:18/ 2019	Potential accelerated approval	SCY-078

Source: Company reports and RBC Capital Market estimates

### Exhibit 4: Pipeline

Product	Mechanism	Stage	Indication	Partner
SCY-078	1,3 beta fl glucan synthesis inhibitor	Phase II anticipated with oral; Phase I with intravenous anticipated	Invasive fungal infections caused by Candida and Aspergillus species	
SCY-635	Cyclophilin inhibitor	Phase IIa	Hepatitis C Virus (HCV)	Waterstone Pharmaceutical
SCYX-7158	Anti-parasitic	Phase I	Human African Trypanosomiasis (Sleeping sickness)	
SCY-641	Cyclophilin inhibitor	Pre-Clinical	Dry Eye disease	

Source: Company reports and RBC Capital Markets estimates

### **Valuation**

We value SCYX at \$17 per share, which includes US and ROW sales of SCY-078. We assign a probability of success of 65% and a value of ~\$6 per share to the US and \$11 per share to the ROW opportunity. We assume a US launch in 2019 and an ROW launch in 2020. Currently, we assume that SCYX will sell SCY-078 in the US and a partner will commercialize these compounds outside the US. We forecast peak SCY-078 sales of \$300-400MM in the US and \$1.0-1.4B in the ROW. We currently assign no additional value to the earlier stage pipeline. Finally, we assume product sales extend into 2030 and include a terminal value based on a terminal growth rate of -50% and a discount rate of 15%.

# **Price target impediments**

Our price target is dependent solely on the clinical, regulatory and commercial success of SCY-078. A Phase II study for SCY-078 is expected in 2014 and data expected in 2015. Failure to demonstrate efficacy or safety in the study would be a significant setback. Furthermore, any setbacks in regulatory approvals in the US or EU, delay in launch, failure to secure a partnership outside the US for SCY-078, increased competition or other limitations to the market potential of these products either due to better efficacy and/or safety outcomes or pricing pressure due to the availability of generic drugs for glaucoma, could negatively impact our valuation.

# **Company description**

SCYNEXIS Inc. (SCYX) SCY-078 treats systemic fungal infections via a new mechanism of action that targets the fungal cell wall. These infections are serious, kill patients, and rates of resistance to current drugs are rising, while all currently available drugs have their limitations, which is the value proposition for SCY-078. The worldwide market for systemic anti-fungals is nearly \$4B. Roughly 600,000 patients are identified with invasive fungal infections and an even higher number is treated. Phase I studies are completed for the oral version and in vitro and in vivo data shows activity in organisms both susceptible and resistant to currently approved drugs. Next up is a Phase II for the oral and a Phase I for the intravenous forms with data in 2015. A Phase II/III study in resistant patients could start in 2016 and potentially provide a more rapid path to the market. SCYX essentially owns all rights to SCY-078, which is patent protected through 2030, as well as to its anti-fungal portfolio. This leaves SCYX free to commercialize the products itself, partner on a global or regional basis, and/or sell the company.



Scynexis - Income Statement

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FYE December 31																	Ad	nan.Butt@r	bccm.com
(in MM; except per share)	2013A	1Q:14A	2Q:14A	3Q:14A	4Q:14E	2014E	1Q:15E	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenue:																			
SCY-078															24.6	46.1	68.4	91.5	115.6
Other Revenue	9.6	4.7	4.6	4.4	4.5	18.2	4.5	4.5	4.5	4.5	18.0	18.1	18.2	18.3	18.4	18.5	18.6	18.7	18.8
Total Revenue	16.9	4.7	4.6	4.4	4.5	18.2	4.5	4.5	4.5	4.5	18.0	18.1	18.2	18.3	43.0	73.1	108.7	145.7	184.2
Operating expenses:																			
Cost of Other Revenue	16.3	4.0	4.2	3.7	4.1	15.9	4.1	4.1	4.1	4.1	16.2	17.5	17.6	17.7	17.8	17.9	18.0	18.1	18.2
R&D	4.4	1.3	1.8	2.5	3.4	9.0	3.3	3.5	3.8	4.5	15.0	20.0	30.0	35.0	25.0	22.5	25.0	27.5	30.0
SG&A	4.4	1.2	2.3	2.0	2.0	7.5	2.0	2.0	2.0	2.0	8.0	8.5	9.0	10.0	22.5	28.8	30.0	32.5	33.1
Other	(1.0)		(0.2)			(0.2)													
Total Expenses	24.1	6.5	8.1	8.2	9.4	32.2	9.3	9.6	9.8	10.6	39.2	46.0	56.6	62.7	67.8	73.8	79.8	87.3	92.9
Operating Expense (income)	(7.2)	(1.8)	(3.5)	(3.8)	(4.9)	(14.0)	(4.8)	(5.1)	(5.3)	(6.1)	(21.2)	(27.9)	(38.4)	(44.4)	(24.7)	(0.7)	28.9	58.5	91.3
Other:																			
Amortization of deferred financing cost and debt discount	3.5	0.5	0.2			0.8													
Interest expense for beneficial conversion feature	10.8		0.0			0.0													
Interest expense-related party	0.9																		
Interest expense	0.2	0.0				0.0													
Derivative fair value adjustment	7.9	(2.8)	(7.3)			(10.1)													
Other income		0.0	1.4		(0.1)	1.3	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)	(0.1)	(0.1)	(0.1)	(0.1)	(0.2)	(0.4)	(0.6)	(0.8)
Income before Tax	(30.5)	0.4	2.2	(3.8)	(5.0)	(21.9)	(4.9)	(5.1)	(5.4)	(6.1)	(21.4)	(28.0)	(38.5)	(44.5)	(24.8)	(0.9)	28.5	57.9	90.5
Taxes																	9.7	19.7	30.8
Net income (loss)	(30.5)	0.4	2.2	(3.8)	(5.0)	(21.9)	(4.9)	(5.1)	(5.4)	(6.1)	(21.4)	(28.0)	(38.5)	(44.5)	(24.8)	(0.9)	18.8	38.2	59.7
Net loss to common stockholders	(46.8)	(1.2)	2.0	(3.8)	(5.0)	(21.9)	(4.9)	(5.1)	(5.4)	(6.1)	(21.4)	(28.0)	(38.5)	(44.5)	(24.8)	(0.9)	18.8	38.2	59.7
Derivative fair value adjustment		(2.8)	(7.3)	_	-	(10.1)	-		-	-	-	7		,	-	-	-	-	-
Net loss to common stockholders (diluted)		(4.0)	(5.3)	(3.8)	(5.0)	(32.0)	(4.9)	(5.1)	(5.4)	(6.1)	(21.4)	(28.0)	(38.5)	(44.5)	(24.8)	(0.9)	18.8	38.2	59.7
EPS, Basic (GAAP)	(\$6.84)	(\$3.65)	\$0.38	(\$0.45)	(\$0.58)	(\$3.88)	(\$0.56)	(\$0.59)	(\$0.62)	(\$0.70)	(\$2.47)	(\$2.02)	(\$2.72)	(\$3.08)	(\$1.26)	(\$0.04)	\$0.91	\$1.82	\$2.79
EPS, Diluted (GAAP)	(\$5.61)	(\$6.57)	(\$0.98)	(\$0.41)	(\$0.53)	(\$5.19)	(\$0.52)	(\$0.54)	(\$0.56)	(\$0.64)	(\$2.27)	(\$1.89)	(\$2.54)	(\$2.87)	(\$1.19)	(\$0.04)	\$0.86	\$1.70	\$2.59
Shares outstanding, Basic	6.8	0.3	5.2	8.5	8.5	5.6	8.6	8.6	8.7	8.7	8.7	13.9	14.2	14.5	19.7	20.1	20.5	21.0	21.4
Shares outstanding, Diluted	8.3	0.6	5.5	9.3	9.3	6.2	9.4	9.4	9.5	9.5	9.4	14.8	15.1	15.5	20.9	21.4	22.0	22.5	23.1
Operating Ratios	2013A	1Q:14A	2Q:14A	3Q:14A	4Q:14E	2014E	1Q:15E	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
COGS															10.0%	10.0%	10.0%	10.0%	10.0%
Gross Margin	NA	NA N	1 AV	1 AV	AV	NA	NA N	1 AV	NA AV	NA .	NA	NA	NA	NA	90.0%	90.0%	90.0%	90.0%	90.0%
R&D	25.9%	28.1%	39.3%	56.6%	75.1%	49.4%	72.2%	77.8%	83.3%	100.0%	83.3%	110.5%	164.8%	191.3%	58.1%	30.8%	23.0%	18.9%	16.3%
SG&A	26.0%	25.6%	48.6%	46.7%	44.4%	41.2%	44.4%	44.4%	44.4%	44.4%	44.4%	47.0%	49.5%	54.6%	52.3%	39.3%	27.6%	22.3%	18.0%
Operating Margin	-42.7%	-37.9%	-74.3%	-86.8%	-109.5%	-76.6%	-106.7%	-112.2%	-117.8%	-134.4%	-117.8%	-154.1%	-211.0%	-242.6%	-57.4%	-0.9%	26.6%	40.1%	49.6%
Taxes	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%
Net Margin	-180.7%	8.8%	48.1%	-86.8%	-110.6%	-120.1%	-107.8%	-113.3%	-118.9%	-135.6%	-118.9%	-154.7%	-211.5%	-243.2%	-57.7%	-1.2%	17.3%	26.2%	32.4%

Source: Company reports and RBC Capital Markets estimates.

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# **Required disclosures**

### **Conflicts disclosures**

The analyst(s) responsible for preparing this research report received compensation that is based upon various factors, including total revenues of the member companies of RBC Capital Markets and its affiliates, a portion of which are or have been generated by investment banking activities of the member companies of RBC Capital Markets and its affiliates.

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A member company of RBC Capital Markets or one of its affiliates managed or co-managed a public offering of securities for SCYNEXIS Inc. in the past 12 months.

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RBC Capital Markets, LLC makes a market in the securities of SCYNEXIS Inc..

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### **Ratings**

**Top Pick (TP):** Represents analyst's best idea in the sector; expected to provide significant absolute total return over 12 months with a favorable risk-reward ratio.

**Outperform (O):** Expected to materially outperform sector average over 12 months.

**Sector Perform (SP):** Returns expected to be in line with sector average over 12 months.

**Underperform (U):** Returns expected to be materially below sector average over 12 months.

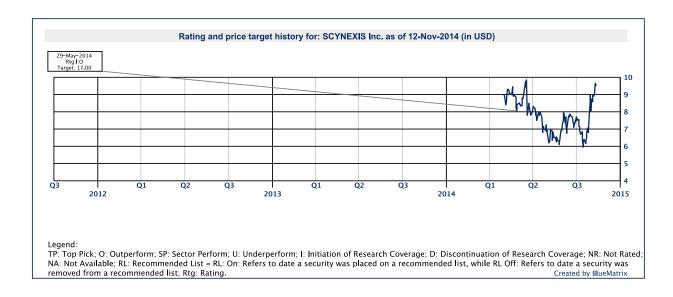
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	Distribution	n of ratings		
	RBC Capital Market	ts, Equity Research		
	As of 30-5	Sep-2014		
			Investment Bank	ing
			Serv./Past 12 Mo	os.
Rating	Count	Percent	Count	Percent
BUY [Top Pick & Outperform]	858	52.35	308	35.90
HOLD [Sector Perform]	683	41.67	151	22.11
SELL [Underperform]	98	5.98	8	8.16



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