

# **RBC Capital Markets**

May 15, 2015

# **SCYNEXIS** Inc.

# New CMO on board; timelines to Phase II data on track for 1H:16

Our view: Overall recent management changes have strengthened the clinical and developmental suite and protocol amendments to the Phase II and management's track record give us confidence in execution along projected timelines. Recent financing has bolstered cash well into 2017 and through Phase II and Phase I data and likely Phase II/III plans. We like shares at current levels given the unmet need and macro tailwinds.

## **Key points:**

- 1Q:15 vs. expectations. Revenues were lower and expenses higher driving a lower than forecast EPS of (\$0.75). Cash at end of 1Q was ~ \$28M and was supplemented with a public offering of ~\$38M net for a pro forma cash position of ~\$76M.
- 2015 guidance vs. consensus. No guidance is provided but we estimate sufficient cash into 2017, past important SCY-078 development events.
- Changes to our estimates. We have not made any significant changes to our forecasts going forward.

### **Key updates from management:**

- Timelines for Phase II oral step-down and Phase I intravenous SCY-078 studies on track. First patient in the Phase II oral step-down study started treatment in March, the enrollment goal is 120 patients across three arms, and the treatment period ranges between 3-10 days on the echinocandin and 14-28 days on SCY-078 or the azole (total is 17-38 days). Results from the oral step-down study are expected in 1H:16.
- Intravenous SCY-078 expected to start Phase I by YE:15. Results are expected around mid-2016. SCYX will apply for QIDP designation in 1H:16 and fast track designation in 2H:16, which we expect SCY-078 to receive (already granted to oral form).
- 2016 is the data year but 2015 should have updates too. Enrollment in the Phase II study will be closely watched since it is post protocol amendments and establishes whether the data is available in 1H:16/ mid-2016 (current guidance) or sooner. Combined these data could allow SCYX to seek approval of and initiate a pivotal Phase II/ III study in resistant organisms by YE:16/ early 2017, start a Phase III in systemic fungal infections, and make the drug available for testing in investigator sponsored studies.
- · New CMO on board; combined management team has lots of antiinfectives experience. The current CEO and new CMO have worked together in the past and have been responsible for the development and approval of several drugs, including both that are anti-fungals and antibiotics. The current CEO also has also had success expediting approval pathways and timelines in his career.

### **Upcoming news flow:**

- SCY-078 Phase II oral data in 1H:16/ mid-2016.
- SCY-078 Phase I i.v. data by mid-2016.

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**Sector: Biotechnology** 

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# Outperform **Speculative Risk**

NASDAQ: SCYX; USD 9.40

## Price Target USD 18.00

WHAT'S INSIDE	
☐ Rating/Risk Change	☐ Price Target Change
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# Scenario Analysis\*

4	Downside Scenario	Current Price	Price Target	Upside Scenario	
	5.00	9.40	18.00	33.00	
	<b>↓</b> 47%		<b>†</b> 91%	<b>↑</b> 251%	

\*Implied Total Returns

### **Key Statistics**

Shares O/S (MM):	9.7	Market Cap (MM):	91
Dividend:	0.00	Yield:	0.0%
		Avg. Daily Volume:	57,990

### **RBC Estimates**

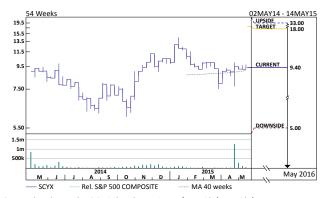
All values in USD unless otherwise noted.

FY Dec	2013A	2014A	2015E	2016E
Revenue	16.9	19.0	15.0	15.1
Prev.			19.1	19.2
EPS, Ops Diluted	(6.84)	(1.04)	(2.23)	(1.57)
Prev.			(1.28)	(1.25)
P/E	NM	NM	NM	NM
Revenue	Q1	Q2	Q3	Q4
2014	4.7A	4.6A	4.4A	5.3A
2015	3.3A	3.6E	3.9E	4.2E
Prev.	4.2E	4.6E	5.0E	5.3E
EPS, Ops Diluted				
2014	(3.65)A	(0.98)A	(0.45)A	(0.36)A
2015	(0.75)A	(0.48)E	(0.52)E	(0.56)E
Prev.	(0.39)E	(0.33)E	(0.28)E	(0.31)E
EPS, Ops Diluted: Basis	c shares used	when EPS a	are negative.	

Priced as of prior trading day's market close, EST (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 \$18 per share, which includes US and ROW sales of SCY-078. We assign a probability of success of 65% and a value of ~\$7 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 \$400-500MM in the US and \$1.3-1.4B in the ROW

### **Upside scenario**

Our upside scenario at \$33 (prev. \$34), includes  $^{\circ}$ \$16 per share in value for the US opportunity and  $^{\circ}$ \$17 per share in value for the ROW opportunity. We forecast peak SCY-078 sales of \$1.0-1.1B in the US and \$2.5-\$2.8B in the ROW. We assign SCY-078 a 65% 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 ~\$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 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: Actual 1Q:15 vs. RBC estimates

(in MM; except per share)	1Q:15A	Est.	Var.
Revenue:			
SCY-078			
Other Revenue	3.3	4.2	(0.9)
Total Revenue	3.3	4.2	(0.9)
Operating expenses:	-	-	
Cost of Other Revenue	3.2	3.8	(0.6)
R&D	4.2	3.3	0.9
SG&A	2.2	0.6	1.7
Other	-	-	-
Total Expenses	9.7	7.6	2.1
Operating Expense (income)	(6.4)	(3.4)	(3.0)
Other:	-	-	-
Amortization of deferred financing cost and debt discount	-	-	-
Interest expense for beneficial conversion feature	-	-	-
Interest expense-related party	-	-	-
Interest expense	(0.0)	-	(0.0)
Derivative fair value adjustment	-	-	-
Other income	-	(0.1)	0.1
Income before Tax	(6.4)	(3.4)	(3.0)
Taxes	-	-	-
Net income (loss)	(6.4)	(3.4)	(3.0)
EPS, Basic (GAAP)	(\$0.75)	(\$0.39)	(\$0.36)
EPS, Diluted (GAAP)	(\$0.73)	(\$0.38)	(\$0.35)
Shares outstanding, Basic	8.5	8.6	(0.1)
Shares outstanding, Diluted	8.7	8.8	(0.1)

Source: Company reports and RBC Capital Markets estimates

Exhibit 3: News flow

Timing	Expected News Flow	Program
2H:15	Initiate Phase I study with i.v. SCY-078	SCY-078
2015	Request QIDP designation for i.v. SCY-078	SCY-078
2015	Potential pipeline related business development	
2015	Phase II update from oral SCY-078 step down study	SCY-078
1H:16/ mid-2016	Phase II results from oral SCY-078 step down study	SCY-078
mid-2016	Phase I intravenous SCY-078 results	SCY-078
2016	Initiate Phase II/III i.v. to oral SCY-078 in relapsed/ refractory patients	SCY-078
YE:16/ 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 Markets 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

# Valuation

We value SCYX at \$18 per share, which includes US and ROW sales of SCY-078. We assign a probability of success of 65% and a value of ~\$7 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 2015 and data expected in 2016. 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	2014E	1Q:15A	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenue:															
SCY-078											19.7	37.7	57.8	80.1	105.0
Other Revenue	9.6	19.0	3.3	3.6	3.9	4.2	15.0	15.1	15.2	15.3	15.4	15.5	15.6	15.7	15.8
Total Revenue	16.9	19.0	3.3	3.6	3.9	4.2	15.0	15.1	15.2	15.3	35.1	64.6	102.4	143.2	187.2
Operating expenses:															
Cost of Other Revenue	16.3	15.4	3.2	3.2	3.5	3.8	13.8	14.5	14.6	14.7	14.8	14.9	15.0	15.1	15.2
R&D	4.4	8.3	4.2	4.6	4.9	5.3	19.0	20.0	30.0	35.0	25.0	22.5	25.0	27.5	30.0
SG&A	4.4	7.6	2.2	2.5	2.7	3.0	10.5	11.0	13.0	15.0	17.5	20.0	25.0	31.3	31.3
Other	(1.0)	(0.2)													
Total Expenses	24.1	31.1	9.7	10.3	11.2	12.1	43.3	45.5	57.6	64.7	59.3	61.2	70.8	81.9	87.0
Operating Expense (income)	(7.2)	(12.1)	(6.4)	(6.7)	(7.3)	(7.9)	(28.3)	(30.4)	(42.4)	(49.4)	(24.1)	3.4	31.6	61.3	100.2
Other:															
Amortization of deferred financing cost and debt discount	3.5	0.8													
Interest expense for beneficial conversion feature	10.8	0.0													
Interest expense-related party	0.9														
Interest expense	0.2	0.0	(0.0)				(0.0)								
Derivative fair value adjustment	7.9	(10.1)													
Other income		1.4		(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)	(4.2)	(6.4)	(6.7)	(7.2)	(7.8)	(28.1)	(30.3)	(42.3)	(49.3)	(24.0)	3.6	32.0	61.9	101.0
Taxes												1.2	10.9	21.0	34.3
Net income (loss)	(30.5)	(4.2)	(6.4)	(6.7)	(7.2)	(7.8)	(28.1)	(30.3)	(42.3)	(49.3)	(24.0)	2.4	21.1	40.8	66.7
Net loss to common stockholders	(46.8)	(5.9)	(6.4)	(6.7)	(7.2)	(7.8)	(28.1)	(30.3)	(42.3)	(49.3)	(24.0)	2.4	21.1	40.8	66.7
Derivative fair value adjustment		(10.1)	-	-	-	-	-	-	-	-	-	-	-	-	-
Net loss to common stockholders (diluted)		(15.9)	(6.4)	(6.7)	(7.2)	(7.8)	(28.1)	(30.3)	(42.3)	(49.3)	(24.0)	2.4	21.1	40.8	66.7
EPS, Basic (GAAP)	(\$6.84)	(\$1.04)	(\$0.75)	(\$0.48)	(\$0.52)	(\$0.56)	(\$2.23)	(\$1.57)	(\$2.14)	(\$2.45)	(\$1.17)	\$0.11	\$0.99	\$1.87	\$3.00
EPS, Diluted (GAAP)	(\$5.61)	(\$2.69)	(\$0.73)	(\$0.47)	(\$0.51)	(\$0.55)	(\$2.19)	(\$1.54)	(\$2.11)	(\$2.41)	(\$1.15)	\$0.11	\$0.97	\$1.84	\$2.93
Shares outstanding, Basic	6.8	5.7	8.5	13.9	14.0	14.1	12.6	19.4	19.7	20.1	20.5	21.0	21.4	21.8	22.2
Shares outstanding, Diluted	8.3	5.9	8.7	14.2	14.2	14.3	12.9	19.6	20.0	20.5	20.9	21.3	21.8	22.3	22.7
Operating Ratios	2013A	2014E	1Q:15A	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	NA	NA N	I Al	NA	NA	NA	NA	NA	90.0%	90.0%	90.0%	90.0%	90.0%
R&D	25.9%	43.6%	127.9%	126.7%	126.7%	125.7%	126.7%	132.5%	197.4%	228.8%	71.1%	34.8%	24.4%	19.2%	16.0%
SG&A	26.0%	39.8%	67.7%	70.0%	70.0%	71.8%	70.0%	72.8%	85.5%	98.0%	49.8%	31.0%	24.4%	21.8%	16.7%
Operating Margin	-42.7%	-63.7%	-193.7%	-186.7%	-186.7%	-187.5%	-188.4%	-201.3%	-278.9%	-322.9%	-68.7%	5.3%	30.9%	42.8%	53.5%
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%
Net Margin	-180.7%	-22.3%	-193.6%	-185.3%	-185.4%	-186.3%	-187.4%	-200.7%	-278.3%	-322.2%	-68.4%	3.7%	20.6%	28.5%	35.6%

Source: Company reports and RBC Capital Markets estimates.

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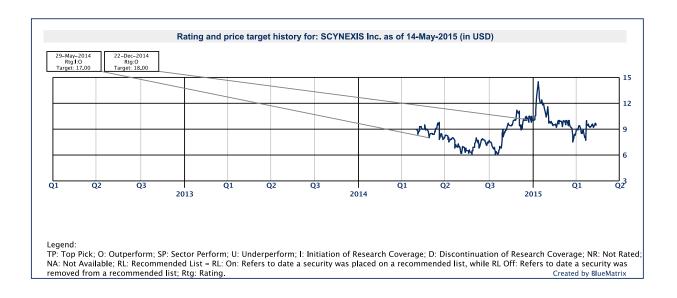
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	Distribution	n of ratings				
	RBC Capital Market	ts, Equity Research				
	As of 31-N	Mar-2015				
			Investment Banking			
			Serv./Past 12 Mo	os.		
Rating	Count	Percent	Count	Percent		
BUY [Top Pick & Outperform]	909	52.33	280	30.80		
HOLD [Sector Perform]	713	41.05	125	17.53		
SELL [Underperform]	115	6.62	5	4.35		



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