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RXi Pharmaceuticals Corp (RXII - NASDAQ)

Dermal & Ocular Assets Available for Sale

Based on our DCF model and a 15% discount rate, RXi Pharmaceuticals is valued at approximately $16.00 per share. Our model applies a 15% probability of ultimate approval and commercialization for RXI-109 and Samcyprone. The model includes contributions from the US, EU and rest of world.

Current Price (8/21/2018)	$1.60
Valuation	**$16.00**

OUTLOOK

RXi Pharmaceuticals has developed a unique composition of interference RNA that is able to self-deliver into the cellular cytoplasm. The compound, sd-rxRNA, combines features of RNAi and antisense, and is able to silence unwanted gene expression with a limited side effect profile.

The company has two Phase II dermal assets and one Phase I/II ocular asset which are expected to be partnered and provide development capital for earlier stage immuno-oncology (IO) programs.

RXi recently directed its main research focus towards its preclinical IO program that is being developed to augment existing cell therapies. A favorable investment and regulatory environment are supportive of IO and should allow for rapid entry into the clinic.

We attach a valuation for the Phase I/II and Phase II assets and expect to see regulatory approvals and subsequent commercialization over the 2022 to 2024 period as described in our analysis.

SUMMARY DATA

52-Week High	**7.70**
52-Week Low	**1.90**
One-Year Return (%)	**-71.0**
Beta	**1.26**
Average Daily Volume (sh)	**339,295**
Shares Outstanding (mil)	**4.38**
Market Capitalization ($mil)	**7.0**
Short Interest Ratio (days)	**2.92**
Institutional Ownership (%)	**27.2**
Insider Ownership (%)	**9.6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2018	$0.0 A	$0.1 A	$0.0 E	$0.0 E	$0.1 E
2019					$0.0 E
2020					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2017	-$2.65 A	-$1.12 A	-$1.05 A	-$0.84 A	-$5.52 A
2018	-$0.90 A	-$0.46 A	-$0.51 E	-$0.53 E	-$2.40 E
2019					-$1.75 E
2020					-$1.79 E

WHAT'S NEW

During the second quarter, RXi obtained additional financing to continue the development of its immuno-oncology program, provided readouts for Samcyprone and RXI-109 in retinal scarring and developed a research collaboration with autologous TIL leader, Iovance. The area of immediate interest is the status of the dermatology and ocular assets which have all provided data available for potential suitors to review. RXi is dependent on an upfront payment from these assets to support the oncology programs that are in development.

On August 14, 2018, RXi Pharmaceuticals (NASDAQ: RXII) reported second quarter 2018 results in conjunction with the filing of their 2Q:18 10-Q. RXi reported revenues of $58,000 for the quarter from grants related to BioAxone's work in spinal cord injury, compared to zero in revenues in 2Q:17. Total expenses were $2.0 million in the period, a decrease from the prior year's $2.5 million.

Research and development expenses were $1.2 million in 2Q:18, down 16% compared with the prior period levels (including acquisition of in-process R&D) due to the wind down of the dermal and ocular trials. No in-process R&D was recognized in 2Q:18, compared to $85,000 2Q:17.

General and administrative expenses fell by 30% to $0.8 million due to decreases in professional fees for legal-related services and payroll-related expenses as a result of a decrease in headcount.

Cash balance as of June 30, 2018 was $5.3 million, down from $3.6 million at year end 2017. Cash burn was ($1.9) million in the April to June period, compared to ($2.5) in the comparable 2017 period. $4.6 million was recognized from financing cash flows, from the April direct equity offering. Management anticipates cash burn to be approximately ($2.0) million per quarter, as the dermatology and ophthalmology programs wrap up and the main focus is directed toward the preclinical IO programs. We see sufficient cash available on the balance sheet to support operations until 2019.

Data and results are available for the entire portfolio of dermatology and ophthalmology assets. A virtual data room has been set up for interested parties and management indicated that they are moving into negotiations with them. RXi has been in contact with approximately 50 companies that are involved with the assets and about 12 of these are currently conducting in-depth due diligence in preparation for a non-binding bid. We cannot predict the actions or interest of other companies, however we do note that the data evidence we have seen so far for the dermatology and ophthalmology programs is very supportive of safety and efficacy and there is a underserved market in each of these areas that can be tremendously profitable. With this background we are hopeful to see the announcement of a deal in the near term.

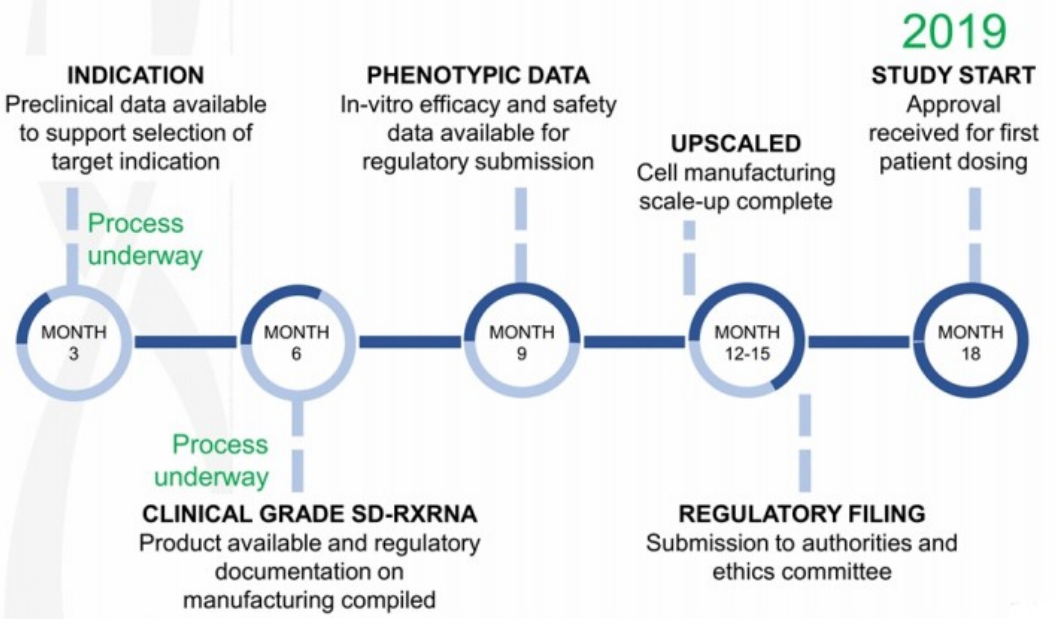
Immuno-oncology Program

Management highlighted its immuno-oncology candidates, including RXI-762, which is being developed to target PD-1 receptors in cell therapy. Current Good Manufacturing Process (cGMP) compliant product will be completed by the end of August. Following close behind RXI-762 is RXI-804, targeting the TIGIT immune receptor, which is present on some T-cells and naturall killer cells. Based on the current state of the development program for IO, the company anticipates having RXI-762 in the clinic in the next 12 to 18 months.

Following the conference call, RXi announced a collaboration with the Karolinska Institutet to develop sd-rxRNA to improve functionality and persistence of T-cells and NK cells. The research will take the next step evaluating TIL antitumor activity against melanoma cells *in vivo*. As with the PD-1 program, the TIL cells receive *ex vivo* treatment with sd-rxRNA to enhance their functionality.

During the quarterly call, Dr. Dispersyn highlighted the three areas of focus in IO, including 1) checkpoint inhibiting sd-rxRNA compounds in T-cell based adoptive cell therapy (RXI-762 & RXI-804), 2) sd-rxRNA enhancement of cancer cell killing in adoptive cell therapy and 3) the use of sd-rxRNA as a monotherapy targeting tumor cells. The first area is being conducted with partners, including CCIT, Medigene and Iovance and is most advanced. The second area is being performed in house with immune effector cells and the company is working to develop external relationships. The third area is focused on identifying targets in the direct tumor and tumor microenvironment with data generation occurring with CROs and academic centers.

Exhibit I – Oncology Assets in the Clinic



Below is the latest pipeline graphic for RXi, which also includes the partnerships that are helping to develop the discovery and preclinical pipeline. The lead aset is RXI-762, which seeks to increase the expression of PD-1 in cell based therapies. Earlier stage programs are targeting the immune receptor TIGIT in solid tumors among other checkpoints. Cell differentiation is another program that is seeking to extend the life of modified immune cells so they will work longer.

Exhibit II – RXi Therapeutic Pipeline

Immuno-Oncology Development Pipeline

INTERNAL	Target	Indication	Disc.	Preclin	Clinical
RXI-762	PD-1*	Solid Tumors			
RXI-804	TIGIT*	Solid Tumors			
Other checkpoints	Multiple*	Solid Tumors			
Cell differentiation	Multiple*	Blood cancers and Solid Tumors			

*In ACT

EXTERNAL	Scope	
CCIT DANMARK	TILs	sd-rxRNA against various cancer types (incl. melanoma, ovarian cancer)
GUSTAVE ROUSSY	Oncology models	sd-rxRNA technology platform for use in cancer treatments
medigene	TCRs	sd-rxRNA and TCRs for next generation of recombinant T cell therapies
PCI Biotech	Combination therapy	Exploring synergies between PCIs fimaNAc and sd-rxRNA
University of Minnesota Driven to Discover	Oncology models	Syngeneic mouse models

Samcyprone

On May 18th RXi Pharmaceuticals issued a press release announcing positive results from their Phase II Samcyprone trial which employs diphenylcyclopropenone (DPCP), a topical immunomodulator that works by initiating a T-cell response to treat common warts. The immunotherapeutic response rate was 97.7% across the 88 patients enrolled in the study. The therapeutic response rate was greater than 70% with once weekly dosing where a therapeutic response was classified as a 50% or greater reduction in wart size. Complete wart clearance was 54% overall and 71% for non-plantar warts. These results compare to a placebo cure rate of 23%.[1] Non-plantar and non-cluster warts showed the best response with a 75% and 73% overall response rate at 10 weeks.

Exhibit III – Wart Response Rate by Class[2]

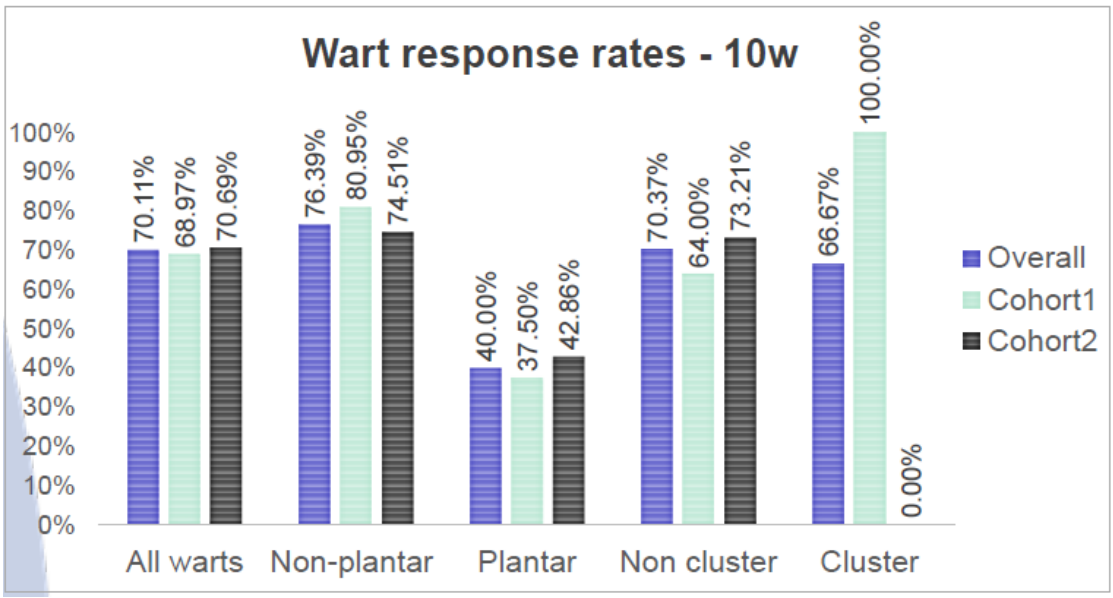
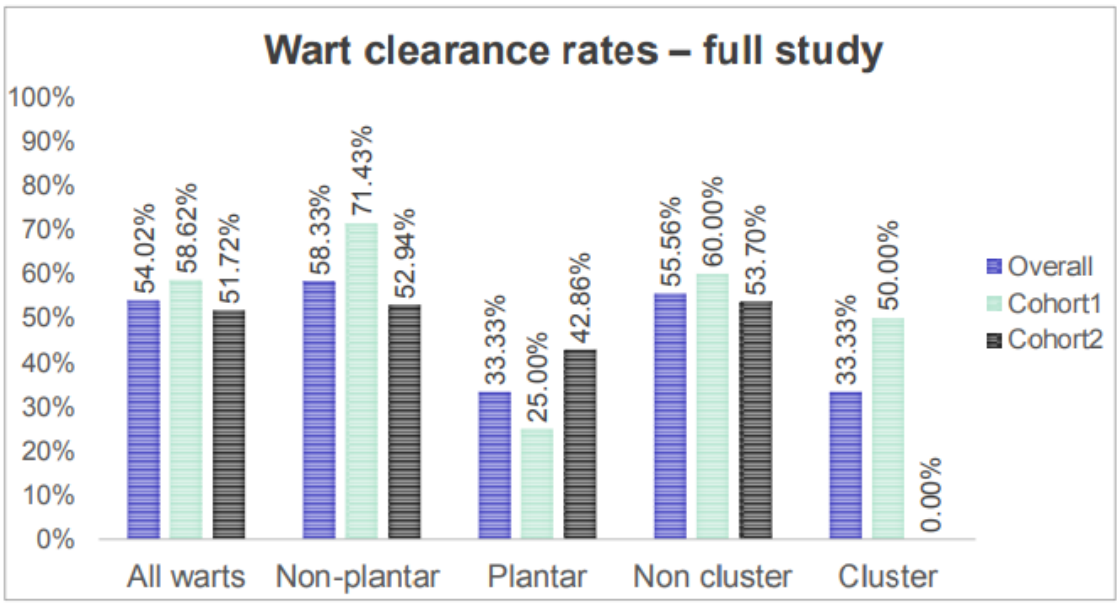


Exhibit IV – Complete Wart Clearance Rates



[1] RXi sourced this data from published meta-analyses.
[2] Bulock, Karen, et al. RXi Pharmaceuticals Poster: Samcyprone (Diphenylcyclopropenone Ointment) for the Treatment of Common Warts.

Safety was confirmed and there were no drug related serious adverse events nor any dose limiting toxicities. Some minor events were noted such as local reaction from the sensitization and challenge responses on the skin.

The medical community is familiar with using DPCP for warts; however, studies had not been conducted to determine a safe and effective dose. The Samcyprone program can obtain FDA approval and exclusivitiy in this indication and exposure to a highly prevalent market for this common skin condition. RXi has made the data from the Phase II trial available for interested partners to review.

Retinal Scarring (RXI-109)

On August 1st RXi Pharmaceuticals issued a press release announcing positive results from their RXI-109-1501 Phase I/II trial for retinal scarring. The primary outcome for the trial was to determine the safety of RXI-109 and to measure the pharmacokinetic profile of the drug in blood. A secondary objective was to measure efficacy of RXI-109 employing a variety of measures. These included change from baseline in subretinal fibrosis lesion size, measure of best corrected visual acuity (BCVA) and relative change of connective tissue growth factor (CTGF) in aqueous fluid compared to baseline.

The safety endpoint was met in the trial. There were a total of 25 adverse events, but the majority were mild and the remaining seven were moderate. No dose limiting toxicities or serious toxicities were observed. Based on the assessment of the investigator, none of the adverse events were related to RXI-109 and five were related to the administration procedure.

More specifically, the safety assessment found **no** instances of:

- clinically significant ocular inflammation (such as 3+ aqueous and vitreous cells)
- retinal toxicities (such as moderate or severe retinal hemorrhages)
- reduction from baseline BCVA ≥30 letters using ETDRS visual acuity charts
- drug related adverse events above Grade 3 or sustained intraocular pressure ≥30 mmHg

The efficacy outcomes were favorable and all but one enrollee showed an improvement in BCVA using early treatment diabetic retinopathy study (ETDRS) tests. The one individual that experienced deterioration on this metric was in the low dose cohort. Below we summarize the BCVA score by cohort.

Exhibit V - RXI-109 Retinal Scarring Results

Dose Cohort	Increase in BCVA	
	Treated Eye	Untreated Eye
Low	+2.3	-
Intermediate	+3.7	-
High	+10.0	-
Total Δ in BCVA	32.0%	4.9%

Subretinal fibrosis lesion size was measured by spectral domain optical coherence tomography. The overall measured reduction in the study was -6.9% with a range of -14.8% to +3.6%. Below we summarize the dose dependent reduction in lesion size by cohort.

Exhibit VI - Central Lesion Thickness Change

Cohort	Δ vs Baseline
Low	-3.8%
Intermediate	-6.7%
High	10.2%
Overall	**-6.9%**

Despite being a small study, the outcome was positive. Safety was confirmed and there was a dose dependent response in the nine patients who participated in the trial.

The results for the RXI-109 Retinal Scarring study were very favorable. Safety was a strong point with no severe adverse events and only Grade I or II adverse events mostly related to administration. Regarding efficacy, fibrous lesions and visual function were both improved compared to baseline in the treated eye. Anti-VEGF treatments for blood vessel growth in the eye were approved based on a standard of avoiding deterioration in vision, rather than improvement. Therefore, the dose dependent improvement in response to RXI-109 is a strong argument for its efficacy if this same standard is applied. While the trial only enrolled nine patients, we interpret the results as strongly supportive of an expanded Phase IIb study. With no other therapies available to treat retinal scarring, RXI-109 is a validated attractive asset that can can provide non-dilutive capital to RXi when sold or partnered.

Capital Raised

Lincoln Park Capital has consistently purchased shares as per their purchase agreement with RXi. For 1H:18, 420,000 shares were issued for $1.3 million. 150,000 shares were issued in 2Q:18 for proceeds of $359,000. In April, RXi registered a direct offering and private placement to raise $4.76 million gross proceeds. 1.51 million shares were issued at $3.15 and 1.2 million warrants were issued with varying exercise prices. HC Wainwright served as the placement agent.

2018 Milestones:

- Capital Draw from Lincoln Park Capital – 1H:18
- Equity capital raise – 2Q:18
- Patent Grant for use of sd-rxRNA targeting CTGF for treatment of fibrotic disorders – May 2018
- Partner Iovance (NASDAQ: IOVA) added for TIL competency – May 2018
- Report of Retinal Scarring trial results – 2Q:18
- Cutaneous Warts study results – May 2018, 2018 at IID
- Retinal Scarring study results – August 2018
- Partnership/Sale of Dermatology and Ophthalmology Programs – 2H:18
- Entry of Immuno-Oncology Programs into the Clinic – Late 2019

In summary, we believe that RXi's sd-rxRNA platform has advanced candidates with convincing safety data and proof of concept for large and lucrative indications. Few competing therapies in scarring and an immense market in warts provide many opporutunities for a global health company to exploit, in turn providing a favorable partnership environment for RXi. The exciting work in immuno-oncology is expected to soon be in the clinic, providing yet another component of value to our current target price. While our valution only accounts for sales of RXI-109 and Samcyprone, the company's other candidates will maintain our focus as they advance.

Summary

The presentation of the Samcyprone and RXI-109 results in retinal scarring are key milestones necessary prior to a transaction with a partner for these assets. Based on management commentary, it appears that there are already a number of interested parties performing due diligence on the dermal and ocular assets. We see sufficient cash on the balance sheet to support operations into 2019, providing sufficient time to negotiate a deal and to obtain upfront cash to support the development of the immuno-oncology assets. During the quarter, RXi raised capital by issuing new debt and warrants, resulting in some dilution. Our target price reflects this change and is now $16.00 per share.

PROJECTED FINANCIALS

RXi Pharmaceuticals Corp. - Income Statement

RXi Pharmaceuticals Corp	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$0.0**	**$0.0**	**$0.1**	**$0.0**	**$0.0**	**$0.1**	**$0.0**	**$0.0**
YOY Growth								
Research & Development	$5.4	$1.4	$1.2	$1.3	$1.4	$5.2	$7.0	$8.0
Acquired In-process R&D	$4.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	
General & Administrative	$4.0	$0.9	$0.8	$0.9	$0.9	$3.5	$4.4	$4.5
Income from operations	($14.1)	($2.2)	($1.9)	($2.2)	($2.3)	($8.6)	($11.4)	($12.5)
Operating Margin	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Interest Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	($0.0)	$0.0	($0.0)	$0.0	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($14.1)	($2.2)	($1.9)	($2.2)	($2.3)	($8.6)	($11.4)	($12.5)
Provision for Income Tax	($1.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*11.5%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($12.5)**	**($2.2)**	**($1.9)**	**($2.2)**	**($2.3)**	**($8.6)**	**($11.4)**	**($12.5)**
			$0.0					
Reported EPS	**($5.52)**	**($0.90)**	**($0.46)**	**($0.51)**	**($0.53)**	**($2.40)**	**($1.75)**	**($1.79)**
YOY Growth								
Basic Shares Outstanding	2.26	2.49	4.10	4.30	4.35	3.81	6.50	7.00

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

RXi Pharmaceuticals Corp. – Share Price Chart

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