**OUTPERFORM** 

Reason for report: **EARNINGS** 

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## RECEPTOS, INC.

3Q13 Updates; Important 4Q13 Interim Phase II RPC-1063 MS; Reit OP

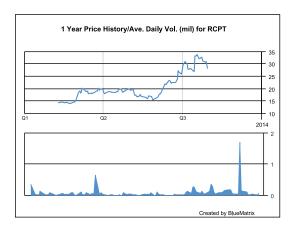
- Bottom Line: 3Q13 updates demonstrate RCPT management is executing well on pipeline initiatives and programs remain on track. An upcoming 4Q13 interim Phase II RPC-1063 ("1063") Multiple Sclerosis (MS) trial analysis that will allow enrollment initiation of the first pivotal Phase III should serve as an important driver because it would mitigate near term downside while positioning investors to benefit from upcoming upside catalysts in 2014. In 2014 we anticipate RCPT will be driven by: 1) potential 1063 partnership (or company M&A); 2) 1063 Phase II MŠ top-line data ~mid-year; 3) 1063 Phase II Ulcerative Colitis (UC) data in 3Q13, and 4) pipeline advancement for RPC-4046. We reiterate an Outperform (OP) rating.
- RCPT reported 3Q13 EPS of (\$0.88) vs. our estimate of (\$0.64). R&D expense was \$13.5M vs. our estimate of \$11.1M. R&D expense was primarily driven by RPC1063 Phase II trial activity and Phase 3 start up costs in RMS, and initiation of the Ulcerative Colitis (UC) Phase II trial. SG&A expense was \$3M vs. our estimate of ~\$2M. RCPT ended 3Q13 with \$80.8M in cash and cash equivalents, which is expected to fund the company through mid-15.
- In 4Q13, we anticipate interim 1063 Phase II data leading to initiation of a Phase III should serve as an important near term catalyst. This interim analysis is primarily focused on safety but will also include early surrogate efficacy observation and will measure 1063 impact on: 1) Heart Rate (HR); 2) liver function tests (LFTs); 3) the trajectory of lymphocyte counts, and; 4) MRI lesion data. A unexpected negative result could lead to a dramatic fall in shares, in our view. On the flip side, we believe a positive result would remove any foreseeable near term negative catalyst and allow RCPT shares to benefit in 2014 from a potential partnership/M&A transaction and Phase II point of care (POC) data read-out for 1063 in MS and UC. On the 3Q13 EPS call management clarified that its next update is likely to be announcement of enrollment commencement in the first Phase III MS trial alongside interim safety and efficacy data.
- While RCPT has a clear path to approval for RPC-1063 in relapsing MS (RMS), we believe there is unleveraged opportunity that could emerge based on choice of different active comparator arms in the second Phase III pivotal RMS trial (link to 6.3 and 8.7 notes). Given a dynamic MS market, swapping the current choice of Avonex for Tecfidera (the current market leader) or Copaxone (possibly going generic soon) could have advantages that a prospective RPC-1063 partner might appreciate in terms of deal economics.

# HEALTHCARE EQUITY RESEARCH

(NASDAQ:RCPT)

**Kev Stats:** 

S&P 600 Health Care Index:	1,190.31
Price:	\$30.89
Price Target:	\$30.00
52 Week High:	\$35.26
52 Week Low:	\$13.00
Shares Outstanding (mil):	18.1
Market Capitalization (mil):	\$559.1
Book Value/Share:	\$0.26
Cash Per Share:	\$4.56
Dividend (ann):	NA



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A					\$8.6					(\$13.73)	NM
2013E - New	\$1.5A	\$1.2A	\$1.1A	\$1.2	\$5.0	(\$5.46)A	(\$0.98)A	(\$0.88)A	(\$0.92)	(\$8.24)	NM
2013E - Old	\$1.5A	\$1.2A	\$1.3	\$1.2	\$5.1	(\$5.46)A	(\$0.98)A	(\$0.64)	(\$0.77)	(\$7.85)	NM
2014E - New					0.0	<b></b>				(\$2.79)	NM
2014E - Old					0.0	<b></b>				(\$2.43)	NM

Source: Company Information and Leerink Swann LLC Research

Revenues in \$000s. Basic shares for '12, PF for 1Q13.



## **INVESTMENT THESIS**

We rate RCPT Outperform. We believe RCPT shares are poised to appreciate near/longer term driven by clinical progress and commercialization of lead compound RPC-1063. Compared to other S1P1 compounds, RPC-1063 is earlier stage but emerging as "best in class." In 2014, RCPT plans to sign an RPC-1063 partnership with large pharma, announce RPC-1063 Phase II data in relapsing MS (RMS) and Ulcerative Colitis (UC) and start two pivotal Phase III RMS trials. We currently assume a 30% probability of approval for RPC-1063 in RMS in 2018. The 2Q13 MEDACorp MS Survey suggests that if approved in 2018, RPC-1063 would take significant market share from Gilenya (~58%), Tecfidera (~13%) and Tysabri (15%) that could be worth \$1.2B in U.S. revenue in 2019E. Core RPC-1063 Intellectual Property (IP) expires in 2029 but Gilenya (NVS) currently goes off patent in 2019. Assuming generic pricing starts in 2020, we model peak risk-adjusted RPC-1063 WW revenues in 2029 of ~\$640M (or \$2.1B non-risk adjusted) which leads to our base case NPV calculation of \$520M (including cash), based only on approval and use in RMS.

## Change in Estimates

We modified our model based on RCPT's earnings release on 10.30.13. Our full-year 2013E revenue changed from \$5.1M to \$5.0M and EPS changed from (\$7.85) to (\$8.24). Our 2014E EPS changed from (\$2.43) to (\$2.79).

### Milestones

Product	Partner	Indication	Phase	Timing	Milestone
				4Q13/1Q14	Initiate Phase III portion of 1 <sup>st</sup> pivotal (RPC01-201), (with SPA)
				4Q13	ECTRIMS updates (i.e. TQTc data)
				2014	Partnership announcement
		Relapsing MS	Phase III	2H14	Initiate 2 <sup>nd</sup> pivotal Phase III RMS trial (with SPA)
				Mid-2014	Phase II data of 1 <sup>st</sup> pivotal (RPC01-201)
RPC-1063	<b>.</b>			2017	2nd pivotal Phase III RMS trial data
(S1P1)	Proprietary			YE17	NDA submission
				2H18	FDA Approval
		Ulcerative		1H14	Complete trial enrollment
			Phase II	3Q14	Phase II UC trial data (might serve as 1 of 2 pivotals)
		Colitis (UC)		2015	Initiate pivotal trial (possibly maintenance)
				2018	Possible NDA submission
RPC-4046		Eosinophilic		4Q13/1Q14	Submit IND
(IL-13)	ABBV	Esophagitis	Phase II	1H14	Initiate Phase II data
(IL-13)		(EoE)		2H15	Phase II trial data

Source: Company Reports, Leerink Swann LLC estimates



## **VALUATION**

We calculate a \$30 DCF price target for RCPT in the next 12 months based on a discounted cash flow (DCF) analysis. We apply a discount rate of 11% and a terminal growth rate of 1% which translates to a 10x terminal multiple which we believe is comparable to biotechnology companies in a similar development stage. We currently assume a 30% probability of approval for RPC-1063 in RMS in 2018. The 2Q13 MEDACorp MS Survey suggests that if approved in 2018, RPC-1063 would take significant market share from Gilenya (~58%), Tecfidera (~13%) and Tysabri (15%) that could be worth \$1.2B in U.S. revenue in 2019E. Core RPC-1063 Intellectual Property (IP) expires in 2029, but Gilenya (NVS) currently goes off patent in 2019. Assuming generic pricing starts in 2020, we model peak risk adjusted RPC-1063 WW revenues of ~\$640M (or \$2.1B non-risk adjusted) which leads to our base case NPV calculation of \$520M (including cash), based only on approval and use in RMS.

## **RISKS TO VALUATION**

An investment in RCPT is fundamentally a high-risk, high-reward investment, in our opinion. RCPT may face significant clinical, regulatory, and commercial risks for pipeline products. Most important is risk associated with potential failure of RPC-1063 (Relapse Remitting Multiple Sclerosis) to obtain regulatory approvals and capture market share in the MS treatment paradigm. RPC-1063 is also the earliest among other S1P receptor modulators. There is also risk that evolving therapeutic landscapes could render RCPT pipeline compounds non-competitive or less valuable once approved.

	RCPT P&L (\$000s, except per share data)																	
	2012A	1Q13A	2Q13A	3Q13A	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenues																		
RPC1063 WW Revenue											\$316,680	\$1,088,253	\$569,241	\$768,848	\$1,003,905	\$1,257,093	\$1,470,700	\$1,664,873
Risk Adjusted RPC1063 WW Revenue											\$95,004	\$326,476	\$170,772	\$230,654	\$301,171	\$377,128	\$441,210	\$499,462
RPC4046																		
Collaborative Revenue	\$8,647	\$1,488	\$1,238	\$1,142	\$1,150	\$5,018	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	\$8,647	\$1,488	\$1,238	\$1,142	\$1,150	\$5,018	-	-	-	-	\$95,004	\$326,476	\$170,772	\$230,654	\$301,171	\$377,128	\$441,210	\$499,462
Costs and Expenses																		
Probability Adjusted COGS	-	-	-	-	-	-	-	-	-	-	\$14,251	\$48,971	\$25,616	\$41,518	\$54,211	\$67,883	\$79,418	\$74,919
R&D	\$22,927	\$8,020	\$9,441	\$13,500	\$14,500	\$45,461	\$50,190	\$85,323	\$110,920	\$124,230	\$134,169	\$138,194	\$142,340	\$146,610	\$149,542	\$152,533	\$155,583	\$158,695
SG&A (Risk Adjusted from Time of RPC1063 Launch)	\$3,430	\$1,062	\$1,589	\$3,050	\$3,100	\$8,801	\$9,505	\$10,265	\$11,087	\$34,369	\$39,000	\$43,400	\$45,570	\$47,849	\$50,241	\$52,753	\$55,391	\$58,160
Total Costs and Expenses	\$26,357	\$9,082	\$11,030	\$16,550	\$17,600	\$54,262	\$59,695	\$95,588	\$122,007	\$158,599	\$187,419	\$230,565	\$213,525	\$235,976	\$253,994	\$273,169	\$290,392	\$291,775
Operating Income (EBIT)	(\$17,710)	(\$7,594)	(\$9,792)	(\$15,408)	(\$16,450)	(\$49,244)	(\$59,695)	(\$95,588)	(\$122,007)	(\$158,599)	(\$92,415)	\$95,911	(\$42,753)	(\$5,322)	\$47,178	\$103,959	\$150,818	\$207,687
Y/Y growth																		
Income Before Taxes	(\$17,710)	(\$9,649)	(\$9,918)	(\$15,565)	(\$16,450)	(\$51,582)	(\$59,695)	(\$95,588)	(\$122,007)	(\$158,599)	(\$92,415)	\$95,911	(\$42,753)	(\$5,322)	\$47,178	\$103,959	\$150,818	\$207,687
Provision for Taxes							- 1	- 1	- 1	- 1	- 1	-	- 1		-	-	-	(21,661)
Net income	(\$17,710)	(\$9,649)	(\$9,918)	(\$15,565)	(\$16,450)	(\$51,582)	(\$59,695)	(\$95,588)	(\$122,007)	(\$158,599)	(\$92,415)	\$95,911	(\$42,753)	(\$5,322)	\$47,178	\$103,959	\$150,818	\$229,348
EPS (LPS) Basic	(\$13.73)	(\$5.46)	(\$0.98)	(\$0.88)	(\$0.92)	(\$8.24)	(\$2.79)	(\$3.50)	(\$3.74)	(\$4.82)	(\$2.78)	\$2.85	(\$1.26)	(\$0.16)	\$1.36	\$2.97	\$4.27	\$6.43
Y/Y growth																		
Basic Shares* (000)	1,290	1,767	10,151	17,715	17,892	6,263	21,404	27,333	32,606	32,932	33,261	33,594	33,930	34,269	34,612	34,958	35,308	35,661

Source: Leerink Swann estimates and company reports.

\* Basic shares for 2012A and 1Q13E are pro forma for IPO priced on 5/8/13.

#### DCF Calcuation

Discount rate	11%
Terminal Growth Rate	1%
Valuation	\$526,504
Valuation / Share	\$30

Source: Leerink Swann estimates.

RCPT DCF Valuation Sensitivity Analysis (\$M)									
	Di	iscount Rate	,						
		9.0%	10.0%	11.0%	12.0%	13.0%			
•	0.0%	\$46	\$36	\$28	\$21	\$16			
Terminal Growth Rate	1.0%	\$51	\$39	\$30	\$23	\$17			
	2.0%	\$57	\$43	\$33	\$25	\$19			
inal	3.0%	\$65	\$48	\$36	\$27	\$21			
Term	4.0%	\$76	\$55	\$41	\$31	\$23			
Source: Leerink Sv		s.							



## Disclosures Appendix Analyst Certification

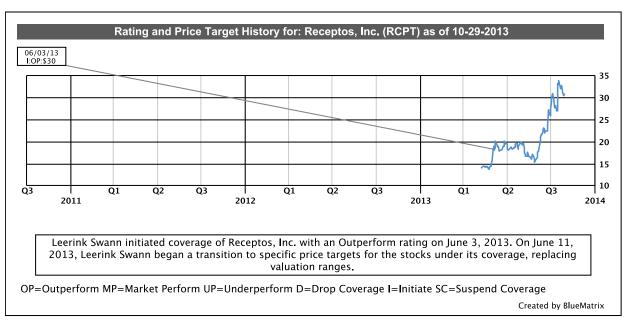
I, Marko Kozul, M.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

## **Valuation**

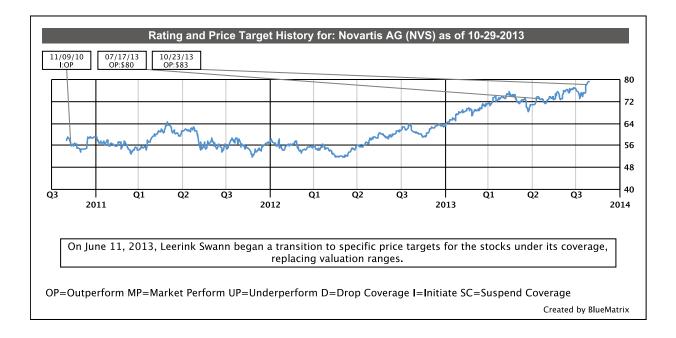
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Distribu	tion of Ratings/Investment Banki	ng Services (IB)		erv./Past 12 Mos.
Rating	Count	Percent	Count	Percent
BUY [OP] HOLD [MP]	111 60	64.90 35.10	27 0	24.00 0.00
SELL [UP]	0	0.00	0	0.00

## **Explanation of Ratings**

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

<u>Market Perform (Hold/Neutral):</u> We expect this stock to perform in line with its benchmark over the next 12 months.

<u>Underperform (Sell):</u> We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

## **Important Disclosures**

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Leerink Swann Consulting LLC, an affiliate of Leerink Swann LLC, is a provider of evidence-based strategy and consulting to the healthcare industry.

In the past 12 months, the Firm has received compensation for providing investment banking services to Receptos, Inc.

RECEPTOS, INC. October 30, 2013



Leerink Swann LLC makes a market in Receptos, Inc.

Leerink Swann LLC is willing to sell to, or buy from, clients the common stock of Novartis AG on a principal basis.

In the past 12 months, an affiliate of the Firm, Leerink Swann Consulting LLC, has received compensation for providing non-securities services to: Novartis AG.

Leerink Swann LLC has acted as a co-manager for a public offering of Receptos, Inc. in the past 12 months.

While IMS Health has been used as a source, the analysis contained herein has been arrived at independently by the firm and IMS is not responsible for the analysis or use of the data.

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