

Reason for report:

EARNINGS

Howard Liang, Ph.D.

(617) 918-4857

Howard.Liang@Leerink.com

Gena Wang, Ph.D.

(212) 277-6073

Gena.Wang@Leerink.com



LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

TESARO, INC.

First Full Quarter as a Public Company Shows Continued Pipeline Progress

• **Bottom Line:** TSRO reported earnings after the close yesterday, and provided a clinical update of its three clinical-stage pipeline products. All three oral rolapitant Phase III trials continue to enroll patients, and the timeline for the data readout remains 2H:13. The IV rolapitant study is anticipated to start imminently. The company anticipates announcing the clinical development program for niraparib by year-end. And finally, the TSR-011 (its ALK inhibitor) is in the process of screening patients for the Phase I dose escalation program. On the financial side, R&D spend was \$11.9M for 3Q:12 compared with our \$13.5M estimate, driving a lower-than-expected loss per share (please see inside for more financial details). TSRO ended the quarter with \$138.6M in cash, which will last it through the rolapitant NDA filing. We maintain our Outperform rating and valuation of \$20 on TSRO.

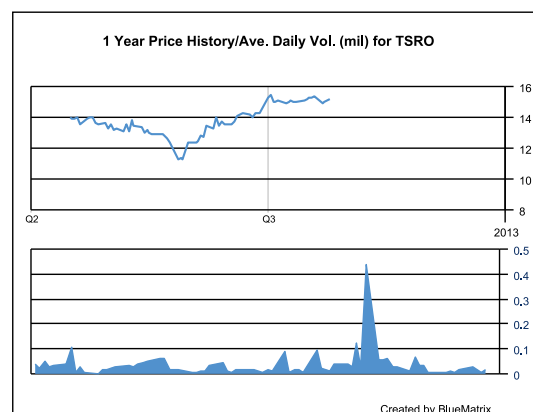
• **TSRO will announce the clinical development program for niraparib by year-end.** Tesaro will announce by year-end its plans for two Phase II trials for Niraparib, its PARP inhibitor, as a monotherapy in two selected patient populations. The company believes, based on the PK profile, the tolerability and the Phase I data, that it has a very competitive PARP inhibitor.

• **TSRO enters the ALK+ race with a highly potent inhibitor.** TSRO has begun screening patients for the dose escalation portion of its Phase I/II clinical trial. TSR-011 is a highly potent ALK inhibitor, which the company will move into Phase II as soon as it determines a dose. The Phase II will consist of three arms with ALK+ patients: 1) a non small cell lung cancer (NSCLC) ALK inhibitor naïve arm, 2) a NSCLC ALK inhibitor refractory arm, and 3) an arm with other tumors types.

Key Stats:

(NASDAQ:TSRO)

S&P 600 Health Care Index:	806.55
Price:	\$15.21
52 Week High:	\$16.34
52 Week Low:	\$11.05
Shares Outstanding (mil):	26.1
Market Capitalization (mil):	\$397.0
Book Value/Share:	\$0.00
Cash Per Share:	\$5.30
Net Debt to Total Capital:	0%
Dividend (ann):	\$0.00
Dividend Yield:	0.0%
Est LT EPS Growth:	NM
Valuation:	\$20 on DCF analysis



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	
2011A	--	--	--	--	0.0	--	--	--	--	(\$1.72)	NM
2012E - New	0.0A	0.0A	0.0A	0.0	0.0	(\$0.70)A	(\$21.31)A	(\$0.52)A	(\$0.64)	(\$4.40)	NM
2012E - Old	0.0A	0.0A	0.0A	0.0	0.0	(\$0.70)A	(\$21.31)A	(\$0.54)	(\$0.60)	(\$4.20)	NM
2013E - New	--	--	--	--	0.0	--	--	--	--	(\$2.38)	NM
2013E - Old	--	--	--	--	0.0	--	--	--	--	(\$2.24)	NM

Source: Company Information and Leerink Swann LLC Research

Estimates reflect conversion of preferred stock into common shares, as well as IPO shares. 2012 Annual EPS reflects change in share count



INVESTMENT THESIS

We rate TSRO shares Outperform with a \$20 valuation based on DCF. We see lead agent rolapitant as a late-stage candidate with modest clinical risk due to proof of principle in the class and a large Phase II trial, and only limited competition relative to many other therapeutic classes. This is matched well with an experienced management team with deep knowledge and a successful track record in the cancer supportive care field. Although the current market of NK-1 antagonist, MRK's Emend, is relatively small, we believe the market potential of the class is significantly larger based on recent strong growth following the approval of intravenous formulations. In addition, due to the pricing and dosing of Emend, sales potential of the class may have been understated. To us, the signal of nausea benefit with rolapitant seen in Phase II is believable due to observed dose response, a smaller effect seen with Emend, and superior pharmacokinetics of rolapitant. We believe rolapitant could be differentiable based on this efficacy advantage together with a better drug-drug interaction profile. Based on our review of the approval history of IV Emend, we believe IV rolapitant has a good chance of success. Lastly, the prior case of Aloxi provided an example of a branded drug in cancer supportive care successfully defending the franchise in a generic environment. For the recently in-licensed PARP inhibitor niraparib, although the failures of the lead agents in the class leave the field without a clear direction, based on MEDACorp key opinion leader feedback we believe this remains an interesting class and niraparib is among the front runners of this class due to good potency, pharmacokinetic profile, and clear clinical single-agent activity. We believe thoughtful patient selection and development strategies could identify a path forward, resulting in the recognition of value for this program, which we believe is not currently in the stock.



TSRO 3Q:12 Variance Table

	<i>LS Est.</i>	<i>Actual</i>	<i>3Q 2012*</i>	<i>Notes</i>
Revenue	\$0.0	\$0.0		
R&D	\$13.5	\$11.9		Slower growth than expected in R&D spend
SG&A	\$2.0	\$1.7		
IPR&D	\$0.0	\$0.0		
Net income	(\$15.5)	(\$13.6)		
EPS	(\$0.54)	(\$0.52)		
Share count	28.89	26.13		

*All numbers in millions except EPS

Sources: Leerink Sw ann estimates, Company reports

TSRO 2012 Estimates

	<i>LS (old)</i>	<i>LS (new)</i>	<i>2012*</i>	<i>Notes</i>
Revenue	\$0.0	\$0.0		
R&D	\$48.7	\$47.1		R&D in 4Q will increase qoq due to rolapitant Phase III trial enrollment and Phase I/II for TSR-011
SG&A	\$6.9	\$6.6		
IPR&D	\$7.0	\$7.0		Upfront cost for niraparib acquisition
Net income	(\$62.5)	(\$60.6)		
EPS	(\$4.20)	(\$4.40)		
Share count	14.89	13.77		

*All numbers in millions except EPS

Sources: Leerink Sw ann estimates, Company reports



VALUATION

Our \$20 valuation is derived from a scenario DCF analysis (with 60% probability of rolapitant showing a nausea benefit, 30% probability of rolapitant showing no nausea benefit, and 10% probability that rolapitant fails), with estimated U.S. sales from 2014 to 2028, the expected patent expiry for rolapitant. We use a discount rate of 10% per year as rolapitant is in a known class of agents and has positive data from a large Phase II trial.

RISKS TO VALUATION

Our risks to valuation include:

- Emend IV and oral generics may impact the rolapitant growth more than we have modeled
- The NK-1 market growth may not continue at the same rates as it has in the recent past
- The nausea benefit that we saw in Phase II of rolapitant may not be replicated in Phase III development, or may not be sufficiently large to hit statistical significance
- The FDA may determine that IV rolapitant may require large Phase III efficacy studies for approval.

TSRO	<u>2011A</u>	<u>1QA</u>	<u>2QA</u>	<u>3QA</u>	<u>4QE</u>	<u>2012E</u>	<u>2013E</u>	<u>2014E</u>	<u>2015E</u>	<u>2016E</u>
Revenue:										
Rolapitant sales								\$1.1	\$37.4	\$147.7
Expenses:										
R&D	11.8	8.2	11.5	11.9	15.5	47.1	55.8	28.0	28.0	20.0
G&A	3.2	1.2	1.7	1.7	2.0	6.6	10.0	10.0	10.0	10.0
S&M								12.5	31.3	31.3
Acquired IPRD	0.5	0.0	7.0	0.0	0.0	7.0	0.0	0.0	0.0	0.0
Total expenses	15.4	9.3	20.2	13.6	17.5	60.7	65.8	50.5	69.3	61.3
Operating income	(15.4)	(9.3)	(20.2)	(13.6)	(17.5)	(60.7)	(65.8)	(49.4)	(31.9)	86.4
Interest income	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.0
Other loss	(1.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	(16.4)	(9.3)	(20.2)	(13.6)	(17.5)	(60.6)	(65.8)	(49.3)	(31.9)	86.5
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Taxes	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Net income	(16.4)	(9.3)	(20.2)	(13.6)	(17.5)	(60.6)	(65.8)	(49.3)	(31.9)	86.5
EPS - common shares	(\$31.90)	(\$13.58)	(\$21.31)	(\$0.52)	(\$0.64)	(\$4.40)	(\$2.38)	(\$1.61)	(\$0.94)	\$2.50
Shares	0.514	0.687	0.947	26.1	27.3	13.77	27.6	30.7	33.9	34.5

*All figures are in millions, except EPS

**Sources: Leerink Swann estimates, Company reports



Disclosures Appendix

Analyst Certification

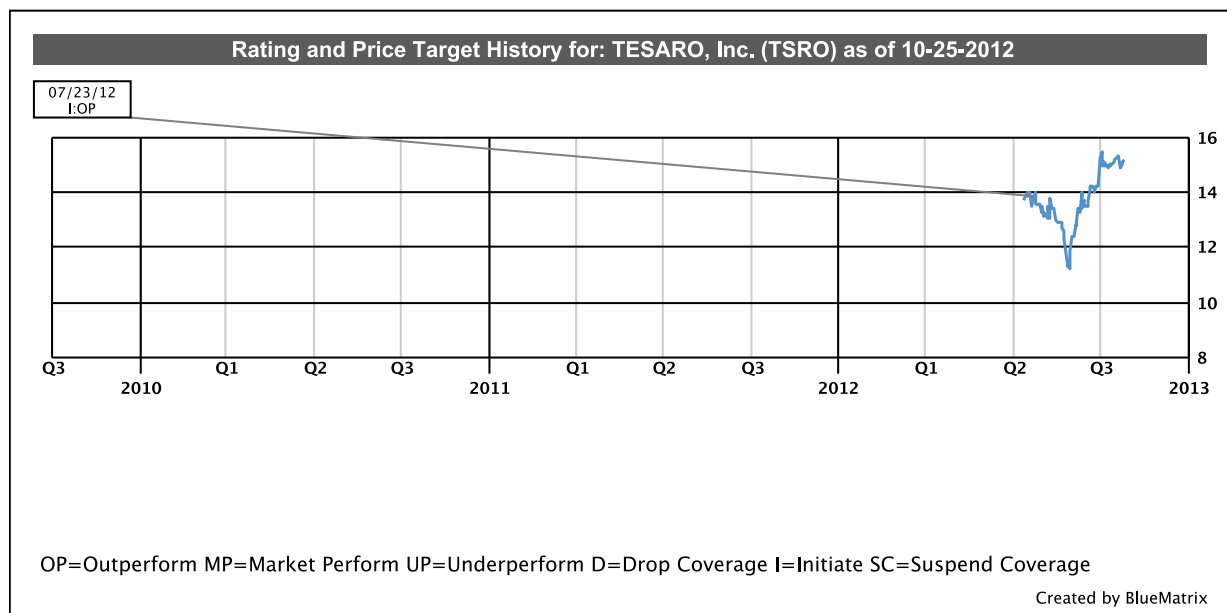
I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

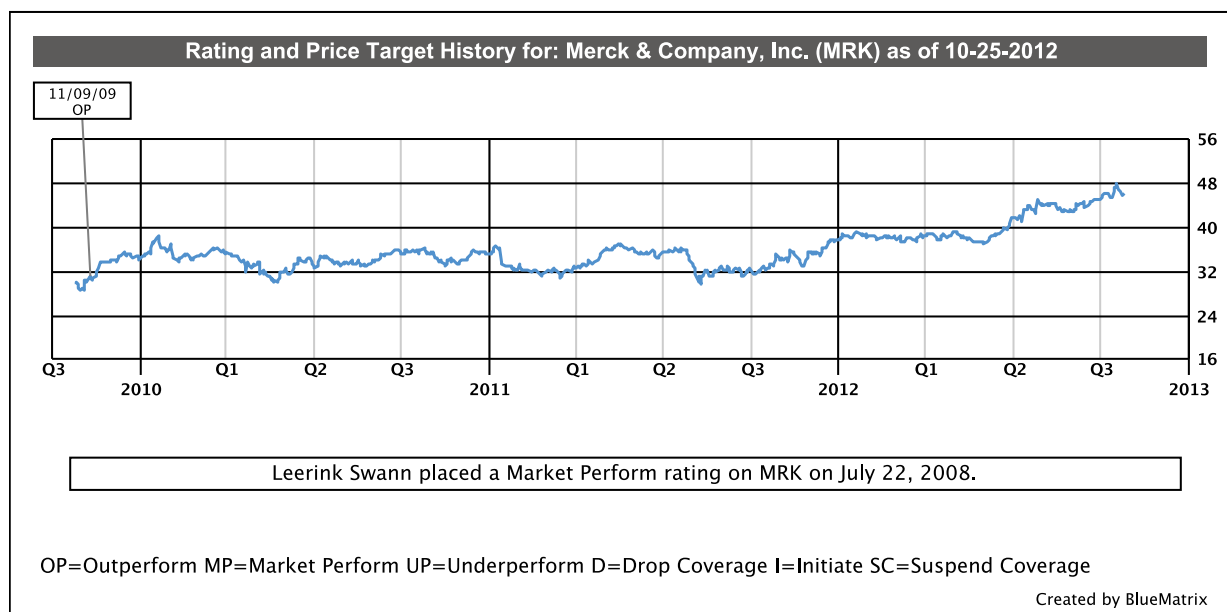
Valuation

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Risks to Valuation

Emend IV and oral generics may impact the rolapitant growth more than we have modeled; the NK-1 market growth may not continue at the same rates as it has in the recent past; the nausea benefit that we saw in Phase II of rolapitant may not be replicated in Phase III development, or may not be sufficiently large to hit statistical significance; the FDA may determine that IV rolapitant may require large Phase III efficacy studies for approval.







Distribution of Ratings/Investment Banking Services (IB) as of 09/30/12				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	102	58.30	29	28.40
HOLD [MP]	73	41.70	3	4.10
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.

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

Underperform (Sell): 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.

From October 1, 2006 through January 8, 2009, the relevant benchmarks for the above definitions were the Russell 2000® 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.

Definitions of Leerink Swann Ratings prior to October 1, 2006 are shown below:

Outperform (Buy): We expect this stock to outperform its benchmark by more than 10 percentage points over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform within a range of plus or minus 10 percentage points of its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark by more than 10 percentage points over the next 12 months.

For the purposes of these definitions, the relevant benchmark were the Russell 2000® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® 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 TESARO, Inc.

Leerink Swann LLC makes a market in TESARO, Inc.

Leerink Swann LLC is willing to sell to, or buy from, clients the common stock of Merck & Company, Inc. on a principal basis.

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

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Leerink Swann LLC Equity Research			
Director of Equity Research	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com
Associate Director of Research	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Healthcare Strategy	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Biotechnology	Howard Liang, Ph.D.	(617) 918-4857	howard.liang@leerink.com
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com
	Marko Kozul, M.D.	(415) 905-7221	marko.kozul@leerink.com
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com
	Irene Lau	(415) 905-7256	irene.lau@leerink.com
	Gena Wang, Ph.D.	(212) 277-6073	gena.wang@leerink.com
Life Science Tools & Diagnostics	Dan Leonard	(212) 277-6116	dan.leonard@leerink.com
	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com
Pharmaceuticals/Major	Seamus Fernandez	(617) 918-4011	seamus.fernandez@leerink.com
	Kathryn Alexander	(617) 918-4568	kathryn.alexander@leerink.com
	Swati Kumar	(617) 918-4576	swati.kumar@leerink.com
Specialty Pharmaceuticals, Generics	Jason M. Gerberry, JD	(617) 918-4549	jason.gerberry@leerink.com
Medical Devices, Cardiology & Orthopedics	Danielle Antalffy	(212) 277-6044	danielle.antalffy@leerink.com
	Richard Newitter	(212) 277-6088	richard.newitter@leerink.com
	Robert Marcus	(212) 277-6084	robert.marcus@leerink.com
	Kathleen McGrath	(212) 277-6020	kathleen.mcgrath@leerink.com
Healthcare Services	Jason Gurda, CFA	(212) 277-6023	jason.gurda@leerink.com
	Jason Twizell	(212) 277-6049	jason.twizell@leerink.com
	George Villarina	(212) 277-6012	george.villarina@leerink.com
Healthcare Technology & Distribution	David Larsen, CFA	(617) 918-4502	david.larsen@leerink.com
	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
Sr. Editor/Supervisory Analyst	Mary Ellen Eagan, CFA	(617) 918-4837	maryellen.eagan@leerink.com
Supervisory Analysts	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com
New York	Boston	San Francisco	
1251 Avenue of Americas, 22 nd Floor	One Federal Street, 37 th Floor	201 Spear Street, 16 th Floor	
New York, NY 10020	Boston, MA 02110	San Francisco, CA 94105	
(888) 347-2342	(800) 808-7525	(800) 778-1164	