

Reason for report:

EARNINGS

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LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

TESARO, INC.

Niraparib Breast Cancer Phase III Adds Another Shot on Goal

• **Bottom Line:** Yesterday after the close, TSRO reported 1Q:13 and provided a pipeline update. TSRO continued its aggressive clinical development of niraparib and announced plans to initiate a Phase III trial of the PARP inhibitor in breast cancer patients with germline BRCA (gBRCA) mutations in 2H:13. With data from 3 rlapitant Phase III studies for chemotherapy-induced nausea and vomiting (CINV) on track to report in 2H:13, and increasing visibility of the broader utility of PARP inhibitors (including upcoming ASCO data), we expect continued investor interest in the coming months. We are incorporating breast cancer sales for niraparib into our model and raising our valuation from \$28 to \$36.

• **Niraparib to move into Phase III in breast cancer, potentially cementing its status as one of the lead candidates in the class.** Data from another PARP inhibitor, olaparib in two Phase II with gBRCA mutation breast cancer patients, demonstrated disparate overall response rate (ORR) results. A study published in Lancet Oncology showed 11/27 (41%) ORR while another study in the Lancet showed 0/8. Though the reason for the discrepancy is unclear, it may be due to small numbers. Importantly, the Lancet study showed tumor shrinkage as best response in 6/8 (75%) with 5 of those being >30%, as well as a 63% clinical benefit rate. TSRO stated that its data in breast cancer, though small numbers, is at least as good as the 41% seen with olaparib in the Lancet paper. Updated data on niraparib in 104 patients will be presented at ASCO this year (abstract #2513).

• **The breast cancer Phase III trial will include 306 gBRCA positive patients randomized 2:1 to niraparib vs. physicians' choice of treatment.** The trial is 95%-powered to detect a HR of 0.5 on PFS and will include a futility analysis. The trial assumes a 6-month PFS in the niraparib arm compared with 3 months in the control arm. Unlike the ovarian cancer study, this study will randomize patients with progressive disease onto niraparib and allow for measurement of overall response as a secondary endpoint.

• **TSR-011 is currently being dosed at 480mg, which should achieve plasma concentrations sufficient for ALK inhibition.** TSRO has submitted an abstract to ESMO for TSR-011, where we will likely see the first clinical data presentation for the compound. Once a maximum tolerated dose is reached for TSR-011, TSRO will initiate 3 parallel cohorts of patients: ALK+ non-small cell lung cancer (NSCLC) patients who have not been previously treated with an ALK inhibitor, those with ALK+ NSCLC who have progressed during treatment with an ALK inhibitor, and those patients with other tumor types that express ALK.

Key Stats:

(NASDAQ:TSRO)

S&P 600 Health Care Index:	918.64
Price:	\$24.40
52 Week High:	\$25.19
52 Week Low:	\$11.05
Shares Outstanding (mil):	32.6
Market Capitalization (mil):	\$795.4
Book Value/Share:	\$0.00
Cash Per Share:	\$6.09
Net Debt to Total Capital:	0%
Dividend (ann):	\$0.00
Dividend Yield:	0.0%
Est LT EPS Growth:	NM
Valuation:	\$36 (prior \$28) on DCF analysis



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	
2012A	0.0	0.0	0.0	0.0	0.0	(\$13.58)	(\$21.31)	(\$0.52)	(\$0.70)	(\$4.51)	NM
2013E - New	0.0A	0.0	0.0	0.0	0.0	(\$0.66)A	(\$0.58)	(\$0.64)	(\$0.64)	(\$2.52)	NM
2013E - Old	0.0A	0.0	0.0	0.0	0.0	(\$0.70)	(\$0.70)	(\$0.70)	(\$0.69)	(\$2.80)	NM
2014E - New	--	--	--	--	\$1.1	--	--	--	--	(\$3.23)	NM
2014E - Old	--	--	--	--	\$1.1	--	--	--	--	(\$1.64)	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 \$36 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, 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 that the announced trial designs in breast and ovarian cancers have reasonable chances of success and applaud the company's aggressive clinical development timelines.

Model updates. We are increasing our 2013E R&D spend to \$70M from \$66M based on company commentary around initiation of a Phase III trial in breast cancer for niraparib. Our new EPS estimate for 2013 is now (\$2.52) compared to (\$2.80) previously due to the increased share count following the March offering. TSRO ended 1Q:13 with \$199M in cash.



TSRO 1Q:13 Variance Table

	1Q 2013*	
	LS Est.	Actual
Revenue	\$0.0	\$0.0
R&D	\$16.5	\$16.5
SG&A	\$2.5	\$2.4
IPR&D	\$0.0	\$0.0
Net income	(\$18.9)	(\$18.9)
EPS	(\$0.70)	(\$0.66)
Share count	26.87	28.80

*All numbers in millions except EPS

Sources: Leerink Swann estimates, Company reports

TSRO 2013 Estimate

	2013*	
	LS Prev. Est.	LS New Est.
Revenue	\$0.0	\$0.0
R&D	\$65.8	\$69.9
SG&A	\$10.0	\$9.9
Net income	(\$75.8)	(\$79.7)
EPS	(\$2.80)	(\$2.52)
Share count	27.08	31.62

*All numbers in millions except EPS

Sources: Leerink Swann estimates, Company reports



VALUATION

We are raising our valuation to \$36 from \$28 previously due to the inclusion of probability-adjusted niraparib sales in breast cancer. We use 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.
- The FDA may not view niraparib as having a positive risk/benefit without overall survival data in their Phase III study.

TSRO	<u>2011A</u>	<u>2012A</u>	<u>1QA</u>	<u>2QE</u>	<u>3QE</u>	<u>4QE</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	47.2	16.5	16.5	18.5	18.5	69.9	86.0	108.0	78.0
G&A	3.2	6.7	2.4	2.5	2.5	2.5	9.9	10.0	10.0	10.0
S&M								12.5	31.3	31.3
Acquired IPRD	0.5	8.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total expenses	15.4	61.9	18.9	19.0	21.0	21.0	79.8	108.5	149.3	119.3
Operating income	(15.4)	(61.9)	(18.9)	(19.0)	(21.0)	(21.0)	(79.8)	(107.4)	(111.9)	28.4
Interest income	0.0	0.2	0.0	0.0	0.0	0.0	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)	(61.8)	(18.9)	(19.0)	(21.0)	(21.0)	(79.7)	(107.3)	(111.9)	28.5
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)	(61.8)	(18.9)	(19.0)	(21.0)	(21.0)	(79.7)	(107.3)	(111.9)	28.5
EPS - common shares	(\$31.90)	(\$4.51)	(\$0.66)	(\$0.58)	(\$0.64)	(\$0.64)	(\$2.52)	(\$3.23)	(\$3.30)	\$0.82
Shares	0.514	13.70	28.8	32.6	32.6	32.6	31.6	33.2	33.9	34.6

*All figures are in millions, except EPS

**Sources: Leerink Swann estimates, Company reports



Disclosures Appendix

Analyst Certification

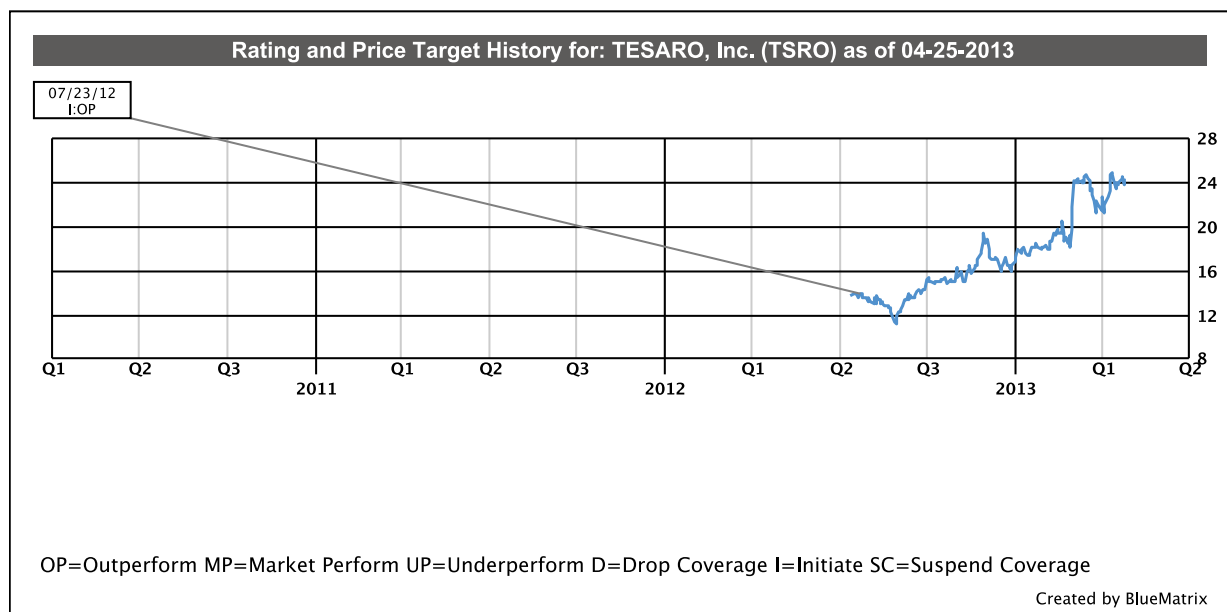
I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

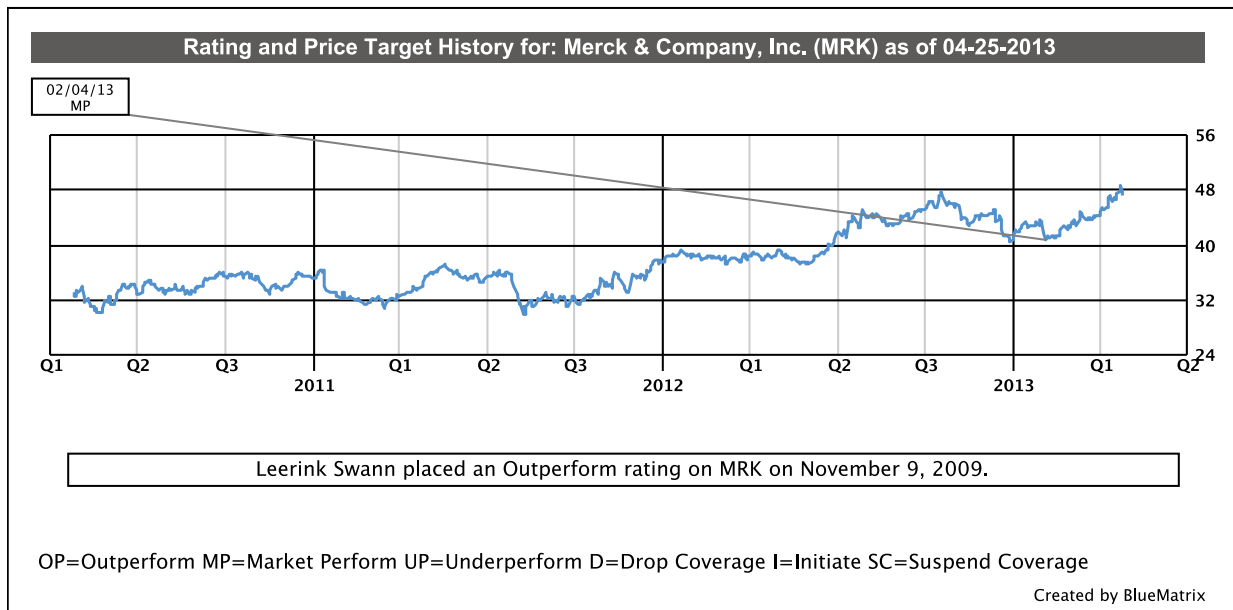
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Risks to Valuation

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; the FDA may not view niraparib as having a positive risk/benefit without overall survival data in their Phase III study.







Distribution of Ratings/Investment Banking Services (IB) as of 03/31/13				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	107	61.14	32	29.91
HOLD [MP]	68	38.86	0	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.

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.

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

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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