#### **OUTPERFORM**

Reason for report:

COMPANY UPDATE

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# TESARO, INC.

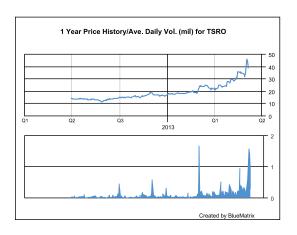
#### Raising Valuation on Supportive ASCO Data

- Bottom Line: Following ASCO, we are updating our TSRO model and raising our valuation from \$36 to \$53 based on higher assumed probabilities of success for rolapitant (for chemotherapy induced nausea and vomiting) and niraparib (PARP inhibitor) as well as broader potential market opportunity for PARP inhibitors. We believe recent ASCO data demonstrate the broad potential opportunities of PARP inhibitors and address an important question with regard to survival benefit. We tabulated available data on PARP inhibitors and we believe our summary shows a competitive profile for niraparib. With two late-stage candidates that each has a good probability of success in our view and is each well matched with management expertise, we believe TSRO is well positioned going into the rolapitant Phase III readout in 2H:13 as well as over the long term due to high operating leverage and synergy.
- Gastric cancer data for olaparib (AZN [MP]) show an overall survival (OS) benefit. ASCO data presented from a 123-patient Phase II trial of paclitaxel +/- olaparib demonstrated a statistically significant OS benefit for the olaparib arm in both the overall population (HR = 0.56, p = 0.01) and the ATM- subset (HR = 0.35, p = 0.003). This OS benefit was surprising given the fact that PFS did not show a statistically significant improvement in either the overall population (HR = 0.80, p = 0.261) or the ATM- subset (HR = 0.74, p = 0.315). Updated OS data from the ovarian study also show a favorable trend despite crossover. We believe that this is proof of concept that appropriately designed studies for PARP inhibitors could demonstrate an improvement in survival.
- PARP inhibitors have strong efficacy in platinum sensitive ovarian cancer, including both BRCA+ and BRCA- patients. With the caveat that comparing across Phase I/II studies is very difficult, it appears that both niraparib and olaparib have strong efficacy in multiple subgroups of ovarian patients but especially the platinum sensitive population (please see our comparison charts inside for more details). Overall, niraparib has 40% ORR in BRCAm ovarian patients compared with 33% (75/225) for olaparib. Efficacy was highest in the platinum sensitive patients and appeared similar for both olaparib and niraparib in BRCAm and BRCAwt patients, though patients numbers are small. BMN-673 activity appears comparable for the platinum sensitive BRCAm patients with a 50% (10/20) response rate. Platinum sensitivity may be a marker of homologous recombinant deficient (HRD) cells that are sensitive to parp inhibitors, even after removing the BRCAm population.



#### HEALTHCARE EQUITY RESEARCH

S&P 600 Health Care	Index:	970.79
Price:		\$38.55
52 Week High:		\$51.95
52 Week Low:		\$11.05
Shares Outstanding (m	nil):	32.6
Market Capitalization (r	mil):	\$1,256.7
Book Value/Share:		\$0.00
Cash Per Share:		\$6.09
Net Debt to Total Capita	al:	0%
Dividend (ann):		\$0.00
Dividend Yield:		0.0%
Est LT EPS Growth:		NM
Valuation:	\$53 (prior \$36) or	n 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	0.0A	0.0	0.0	0.0	0.0	(\$0.66)A	(\$0.58)	(\$0.64)	(\$0.64)	(\$2.52)	NM
2014E - New					\$1.1	<b></b>				(\$3.24)	NM
2014E - Old					\$1.1					(\$3.23)	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 \$53 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 (MP) 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, the same effect seen with netupitant, and the 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. The PARP inhibitor 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 Phase III trial designs in breast and ovarian cancers have reasonable chances of success, and we applaud the company's aggressive clinical development timelines.

Updated Phase II data for the olaparib ovarian maintenance study (ASCO Abstract 5505) suggests that the niraparib Phase III is well powered for both the BRCAm and BRCAwt cohorts. Retrospective analysis of the olaparib ovarian maintenance study showed that olaparib improved PFS in both BRCAm and BRCAwt patients with HR = 0.18 and 0.53, respectively. The niraparib Phase III ovarian study includes both BRCAm and BRCAwt cohorts and is powered for a HR of 0.5, but a HR as high as 0.7 still has a good chance.

Activity by multiple PARP inhibitors in metastatic breast cancer (mBC) validates the rationale of niraparib's Phase III development program despite limited data in this indication. Niraparib demonstrated tumor reduction in 50% (2/4) BRCAm breast cancer patients in Phase I, which while encouraging is a small sample upon which to design a Phase III study. However, efficacy has also been shown with olaparib (13%), rucaparib (13%) and BMN-673 (39%) suggesting that in this genetically defined population parp inhibitors have efficacy. Though the olaparib ORR is relatively low, it may understate the effect of the agent as some patients had tumor reductions that were not confirmed on subsequent visits or progression of non-target or new lesions at the same visit (Gelman, Lancet Oncology 2011). Olaparib is also being studied in breast cancer with studies in mBC as well as the neoadjuvant and adjuvant setting.

Preclinical data suggest that Niraparib may have differential properties from other PARP inhibitors in development. Recent data published suggest that PARP inhibitor may have effects through DNA trapping (Murai, Cancer Research 2012). Niraparib was found to be more potent than olaparib (AZN) and ABT-888 (ABBV, NR) on this measure, potentially explaining why it has efficacy in BRCA-WT patients. We are not aware of data on how niraparib compares to BMN-673 (BMRN, OP) or rucaparib (CLVS, OP) on this measure of efficacy. It remains unclear how this



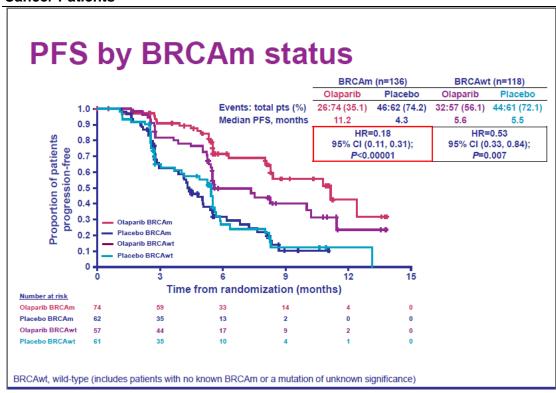
aspect of activity is correlated with the efficacy or the mechanism of action of PARP inhibitors, which is thought to be promoting nonhomologous end joining.

Alliances with breast cancer and ovarian cancer cooperative groups could help to accelerate Phase III trials. Over the weekend, TSRO announced partnerships with the European Network of Gynecological Oncological Trial Groups (ENGOT), Breast International Group (BIG), a non-profit organization for academic breast cancer research groups from around the world, and the European Organization for Research and Treatment of Cancer (EORTC) to facilitate the enrollment of its Phase III studies of its PARP inhibitor niraparib. As PARP inhibitor space is competitive and the speed to market is of essence, we believe this could potentially be an important development.

Netupitant (Netu) statistically significant benefit on nausea bodes well for rolapitant's upcoming Phase III data. Netu/Aloxi (Helsinn) combination demonstrated superiority to Aloxi in Phase III moderately emetogenic (MEC) chemotherapy-induced nausea and vomiting (CINV) with a 75% no nausea rate compared with 69% (p-value 0.02). We believe that this establishes proof of principle for NK-1 receptor antagonists, establishing an additional nausea benefit, and bodes well for rolapitant's upcoming Phase III data. We note that the Netu Phase III was 1,455 patients, very similar to the 1,350 in rolapitant's study. Furthermore, rolapitant trials used Kytril as the comparator, which has only established efficacy for 24 hours and was only dosed for 3 days in this study. Aloxi has established efficacy over 120 hours with a single dose. Therefore, we believe that Kytril is an easier comparator than Aloxi and should further help rolapitant's chances. Though both Netu and rolapitant may have a nausea benefit, rolapitant will be the only agent with an IV formulation, which is currently 80% of the market. Furthermore, according to our discussions with Helsinn representatives, Netu/Aloxi's filing for highly emetogenic chemotherapy (HEC) will be based on a Phase II trial, and apparently the FDA has stated that it could sufficient for a HEC claim. In contrast, TSRO has two ongoing Phase III trials in HEC in addition to the MEC trial, therefore will have a more robust data package. The emergence of immunotherapy for cancer may have raised questions about the future of supportive care for chemotherapy such as rolapitant. However, we note that the biggest use for CINV (chemotherapy-induced nausea and vomiting) agents is in breast cancer, and there is currently limited data suggesting utility of immunotherapy in breast cancer.



# Olaparib Demonstrated PFS Benefit in Both BRCAm and BRCAwt Ovarian Cancer Patients



Source: Lederman, ASCO 2013



# Olaparib and Niraparib Have Efficacy in Platinum Sensitive Ovarian Cancer Regardless of BRCAm Status

			Ovarian Cancer									
				<u>Platinum Sensitive</u>								
			<u>All</u>	All BRCAM BRCAM BRCAWt BRCAWt								
Compound	Company	<u>Phase</u>	RECIST	CA-125	RECIST	CA-125	RECIST	CA-125				
Olaparib	AZN	Phase III	53% (8/15) <sup>3</sup>	55% (11/20) <sup>3</sup>	60% (3/5) <sup>3</sup>	100% (5/5) <sup>3</sup>	50% (5/10) <sup>3</sup>	40% (6/15) <sup>3</sup>				
Niraparib	TSRO	Phase III	46% (6/13) <sup>¤</sup>		50% (5/10)		33% (1/3)					
Rucaparib*	CLVS	Phase II										
BMN-673	BMRN	Phase I			50% (10/20)	77% (17/22)						

<sup>&</sup>lt;sup>¤</sup> At Phase III dose 75% (3/4)

Sources: (Niraparib - Michie, ASCO 2013 and Schelman ASCO 2011); (Rucaparib - Kristeleit, ASCO 2013); (BMN 673 - de Bono, ASCO 2013); (ABT-888 - Huggins-Puhalla, ASCO 2012); (1: Olaparib - Fong, NEJM 2009 and 2: Kaufman, ASCO 2013 and 3: Gelmon, Lancet 2011)

 $<sup>{\</sup>bf *Measurable\ disease\ not\ required\ for\ study\ entry}$ 



## Parp Inhibitors Have Limited Efficacy in Platinum Resistant BRCAwt Ovarian Cancer

				Ovarian Cancer									
				<u>Platinum Resistant</u>						Platinum Sensitive/Resistant/Refractory			
			<u>All</u>	All BRCAM BRCAM BRCAWT BRCAWT				BRCAm	BRCAm	BCRA-	BCRA-		
<u>Compound</u>	Company	<u>Phase</u>	RECIST	CA-125	RECIST	CA-125	RECIST	CA-125	RECIST	CA-125	RECIST	CA-125	
Olaparib	AZN	Phase III	13% (5/38) <sup>3</sup>	18% (6/34) <sup>3</sup>	33% (4/12) <sup>3</sup>	18% (2/11) <sup>3</sup>	4% (1/26) <sup>3</sup>	17% (4/23) <sup>3</sup>	33% (75/225) <sup>1,2,3</sup>	42% (13/31) <sup>1,3</sup>	22% (11/51) <sup>1,3</sup>	26% (10/38)	
Niraparib	TSRO	Phase III	11% (3/27)	22% (6/27)^	33% (3/9)		0% (0/18)		40% (8/20)		40% (2/5)		
Rucaparib*	CLVS	Phase II							14% (1/7)				
BMN-673	BMRN	Phase I			20% (1/5)	33% (2/6)**			44% (11/25)	70% (19/27) <sup>§</sup>			

<sup>&</sup>lt;sup>¤</sup> At Phase III dose 75% (3/4)

§27 patients total evaluable but 22 platinum sensitive and 6 resistant/refractory according to slides

Sources: (Niraparib - Michie, ASCO 2013 and Schelman ASCO 2011); (Rucaparib - Kristeleit, ASCO 2013); (BMN 673 - de Bono, ASCO 2013); (ABT-888 - Huggins-Puhalla, ASCO 2012); (1: Olaparib - Fong, NEJM 2009 and 2: Kaufman, ASCO 2013 and 3: Gelmon, Lancet 2011)

<sup>\*</sup>Measurable disease not required for study entry

<sup>^</sup>Response by RECIST and/or CA-125

<sup>\*\*</sup>Platinum resistant/refractory



# Multiple Parp Inhibitors Have Shown Efficacy in BRCAm Breast Cancer

			Breast (	Cancer	Prostate Cancer		rostate Cancer Pancreatic Cancer		Across All Tu	mor Types	
			<u>BRCA</u>	Non-BRCA	<u>BRCA</u>		<u>BRCA</u>	<u>B</u>	<u>RCA</u>	BRC	<u>AwtWT</u>
	Company	Stage of Development	RECIST	RECIST	RECIST	>30% CTC decline	RECIST	RECIST	Tumor-Marker	RECIST	Tumor-Marker
Olaparib	AZN	Phase III	21% (19/89)†	0% (0/15)	50% (4/8)		22% (5/23)	31% (98/312)	37% (7/19)	11% (11/98)	0% (0/37)
Niraparib	TSRO	Phase III	50% (2/4)			70% (7/10)		42% (10/24)		40% (2/5)	
Rucaparib*	CLVS	Phase II	13% (1/8)					13% (2/15)			
ABT-888	ABBV	Phase II						10% (3/31)		4% (1/25)	
BMN-673	BMRN	Phase I	39% (7/18)					39% (18/46)			

<sup>\*</sup>Measurable disease not required for study entry

Sources: (Niraparib - Michie, ASCO 2013 and Schelman ASCO 2011); (Rucaparib - Kristeleit, ASCO 2013); (BMN 673 - de Bono, ASCO 2013); (ABT-888 - Huggins-Puhalla, ASCO 2012); (Olaparib - Fong, NEJM 2009 and Kaufman, ASCO 2013 and Tutt, Lancet 2010 and Gelmon, Lancet 2011)

<sup>^47% (9/19)</sup> in Phase I and 29% (78/266) in Phase II)

<sup>†</sup>Includes both Kaufman and Tutt studies

<sup>\*\*</sup>Platinum resistant/refractory



# Pipeline

Product	Mechanism	<u>Indication</u>	Stage
Rolapitant	NK-1 receptor antagonist	CINV in HEC treated patients	Phase III
Rolapitant	NK-1 receptor antagonist	CINV in MEC treated patients	Phase III
Niraparib	Parp Inhibitor	Ovarian Cancer	Phase III to initiate mid-2013
Niraparib	Parp Inhibitor	Breast Cancer	Phase III to initiate 2H:13
TSR-011	ALK Inhibitor	NSCLC, other tumor types	Phase I

 ${\it CINV-chemotherapy induced nausea and vomiting, HEC-highly emetogenic chemotherapy, MEC-moderately emetogenic chemotherapy} \\ Source: Company reports$ 

# **Company Events**

Event	Timing
Niraparib Phase III ovarian enrollment begins	mid 2013
Phase III Rolapitant data readout	2H:13
Niraparib Phase III breast cancer enrollment begins	2H:13

Source: Company reports



#### **VALUATION**

We are raising our valuation to \$53 from \$36 previously due to probabilities of success for niraparib and rolapitant. We use a scenario DCF analysis (with 75% probability of rolapitant showing a nausea benefit, 20% probability of rolapitant showing no nausea benefit, and 5% probability that rolapitant fails), with estimated U.S. sales from 2014 to 2028, the expected patent expiry for rolapitant. We also include probability adjusted sales for niraparib in gastric, ovarian and breast cancer. We use a discount rate of 10% per year as rolapitant and niraparib are from a known class of agents with validated efficacy.

### **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>2013E</u>	2014E	<u>2015E</u>	<u>2016E</u>
			<u>1QA</u>	<u> 2QE</u>	<u>3QE</u>	4QE				
Revenue:										
Rolapitant sales								\$1.1	\$37.4	\$147.7
Niraparib sales										\$10.9
Expenses:										
COGS								0.2	6.6	28.1
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	108.7	155.9	147.3
Operating income	(15.4)	(61.9)	(18.9)	(19.0)	(21.0)	(21.0)	(79.8)	(107.6)	(118.5)	11.3
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)	(107.5)	(118.5)	11.3
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)	(107.5)	(118.5)	11.3
EPS - common shares	(\$31.90)	(\$4.51)	(\$0.66)	(\$0.58)	(\$0.64)	(\$0.64)	(\$2.52)	(\$3.24)	(\$3.50)	\$0.33
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,	•									
**Sources: Leerink Swann	estimates, C	Company re	ports							

<sup>10</sup> 

TESARO, INC. June 7, 2013



# **Disclosures Appendix Analyst Certification**

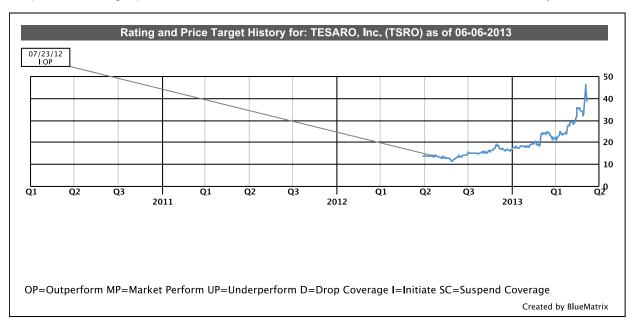
I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

#### **Valuation**

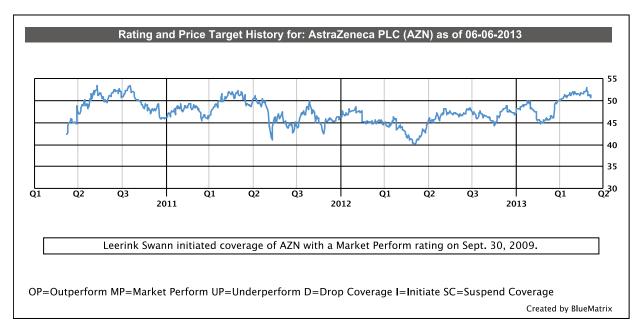
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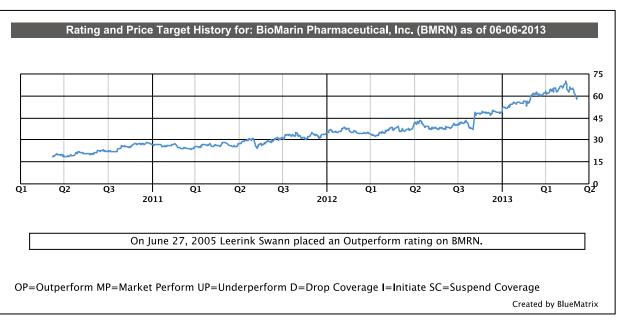
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Emend IV and oral generics may impact the rolapitant growth more than we have modeled; the NK-1 market growth may not continue at the same rates as it has in the recent past; the nausea benefit that we saw in Phase II of rolapitant may not be replicated 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.

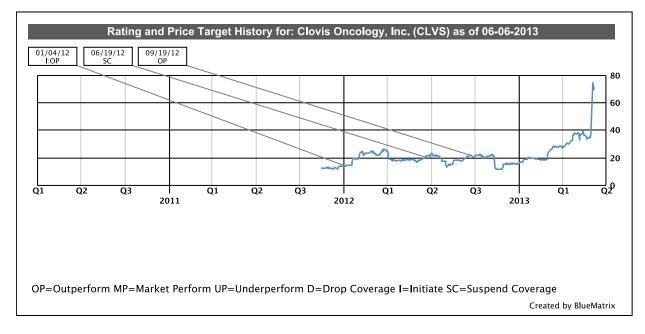


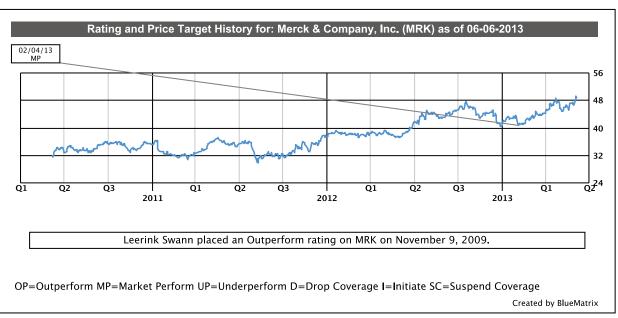












TESARO, INC. June 7, 2013



Dist	ribution of Ratings/Investment Bank	king Services (IE	,	erv./Past 12 Mos.
Rating	Count	Percent	Count	Percent
BUY [OP] HOLD [MP]	107 68	61.14 38.86	32 0	29.91 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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Like all Firm employees, analysts receive compensation that is impacted by, among other factors, overall firm profitability, which includes revenues from, among other business units, the Private Client Division, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction.

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.

TESARO, INC. June 7, 2013



Leerink Swann LLC makes a market in TESARO, Inc., BioMarin Pharmaceutical, Inc. and Clovis Oncology, Inc. Leerink Swann LLC is willing to sell to, or buy from, clients the common stock of AstraZeneca PLC and 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: AstraZeneca PLC and 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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