February 14, 2013

## Biotechnology

Jim Birchenough, M.D.

BMO Capital Markets Corp. 415-591-2129 jim.birchenough@bmo.com

Chuck Whitesell / Nick Abbott, PhD.

## **Tesaro**

(TSRO-NASDAQ)

Stock Rating: Outperform Industry Rating: Outperform

# Pipeline Visibility Accelerating and CINV Phase 3 Approaches

#### **Event**

Tesaro reported 4Q12 operating results earlier today and provided an update on key initiatives on a call with investors. Non-GAAP loss per share of \$0.70 was generally in line with \$(0.65) consensus, and TSRO ended 2012 with \$125M in cash. With focus on pipeline progress, the rolapitant phase 3 program in chemotherapy induced nausea and vomiting (CINV) remains on track for data release in 2H13 with two studies in patients received highly emetogenic chemotherapy (HEC) and one study in patients receiving moderately emetogenic chemotherapy (MEC). Progress with earlier-stage programs was also described with ALK-inhibitor TSR-011 moving into a fourth dosing cohort where inhibition of ALK is expected and where ALK+ patients will be studied, and where phase 3 initiation by mid-year was described for PARP inhibitor niraparib in patients with platinum sensitive, relapsed serous ovarian cancer. The phase 3 study for niraparib was of particular focus on the call, and TSRO described a 360-patient maintenance study randomized 2:1, niraparib vs placebo, in patients achieving response with platinum agent and equally divided between BRAC+ and BRCA- status.

#### **Impact**

We are reiterating our Outperform rating on shares of TSRO, following a better-than-expected 4Q12 update. Progress with niraparib from phase 1 dose escalation to a pivotal phase 3 puts the company ahead of competitors with significant prior validation of PARP inhibition in advanced ovarian cancer. With phase 3 data for rolapitant and early data for ALK+ patients with TSR-011 in 2H13, we see several opportunities for meaningful value appreciation in TSRO shares.

#### **Forecasts**

Our 2013 forecast is for a loss per share of \$2.35.

#### **Valuation**

Our \$22 target is based on 20x our 2017E EPS of \$2.35 discounted 25%.

#### Recommendation

We rate Tesaro Outperform.

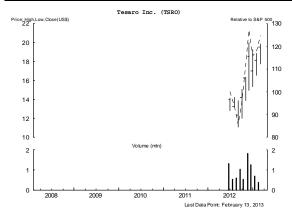
Changes

**Annual EPS** 2013E -\$2.30 to -\$2.35 2014E -\$2.51 to -\$2.57

#### **Securities Info**

Price (13-Feb)	\$19.48	Target Price	\$22
52-Wk High/Low	\$20/\$11	Dividend	
Mkt Cap (mm)	\$520	Yield	
Shs O/S (mm, BASIC)	26.7	Float O/S (mm)	8.5
Options O/S (mm)	na	ADVol (30-day, 000s)	37

#### **Price Performance**



#### Valuation/Financial Data

(FY-Dec.)	2011 A	2012A	2013E	2014E
EPS GAAP	-\$31.90	-\$4.51	-\$2.35↓	-\$2.57↓
P/E			nm	nm
First Call Cons.		-\$3.64	-\$2.38	-\$2.13
FCF	-\$14.24	-\$47.73	-\$66.00	na
P/FCF			nm	na
EBITDA (\$mm)	-\$15	-\$62	-\$65	-\$81
EV/EBITDA			nm	nm
Rev. (\$mm)	\$0	\$0	\$0	na
EV/Rev			na	na
Quarterly EPS	1Q	2Q	3Q	4Q
2012A	-\$0.70	-\$21.31	-\$0.52	-\$0.70
2013E	-\$0.53	-\$0.58	-\$0.60	-\$0.65
Balance Sheet Da	ta (30-Sep)			
Net Debt (\$mm)	-\$125	TotalDe	bt/EBITDA	nm
Total Debt (\$mm)	\$0	EBITDA	/IntExp	na
Net Debt/Cap.	nm	Price/Bo	ook .	4.5x

Notes: Quarterly EPS may not sum due to share count. All values in US\$.

Source: BMO Capital Markets estimates, Bloomberg, Thomson Reuters, and IHS Global Insight.

Quarter	ly El	PS
---------	-------	----

Q1/13E na to -\$0.53 Q2/13E na to -\$0.58 Q3/13E na to -\$0.60 Q4/13E na to -\$0.65 BMO Capital Markets Tesaro

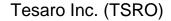
## Exhibit 1: TSRO Income Statement 2011-2017E

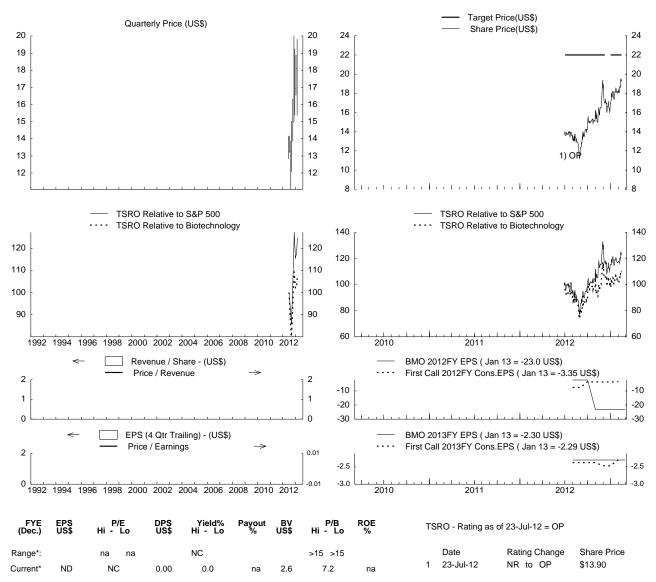
INCOME STATEMENT (\$M)	2012A	1Q13E 2Q13E		3	Q13E	4Q13E		2013E		2014E		2015E			2016E		2017E		
REVENUES																			
Product Revenues	\$ -	\$	-	\$ -	\$	-	\$	-	\$	-	\$	-	\$	4	3.3	\$	129.9	\$	318.4
Collaborative Revenues/Milestones	-		-	 -		-	_	-		-		-	L		-	_	-		-
Total Revenues	\$ -	\$	-	\$ -	\$	-	\$	-	\$	-	\$	-	\$	4	3.3	\$	129.9	\$	318.4
EXPENSES (GAAP)																			
Cost of Goods Sold (COGS)	\$ -	\$	-	\$ -	\$	-	\$	-	\$	-	\$	-	\$		0.2	\$	0.4	\$	0.7
R&D Expense	47.2		12.2	13.2		14.0		14.9		54.3		66.2		7	3.1		90.4		100.4
SG&A Expense	6.7		2.1	2.6		2.6		3.2		10.5		14.5		5	3.0		69.0		114.0
Acquired In-Process R&D	8.0		-	-		-		-		-		-			-		-		-
TOTAL EXPENSES	61.9		14.3	15.8		16.6		18.1		64.8		80.7		13	1.2		159.8		215.1
Operating Income	(61.9)		(14.3)	(15.8)		(16.6)		(18.1)		(64.8)		(80.7)		(8)	7.9)		(29.8)		103.3
Depreciation and Amortization	-		-	 -		-		-		-		-					-		-
EBIT	(61.9)		(14.3)	(15.8)		(16.6)		(18.1)		(64.8)		(80.7)		(8	7.9)		(29.8)		103.3
Interest Income	0.2		0.2	0.2		0.1		0.1		0.6		0.1		(	0.0)		(0.1)		(0.1)
Interest Expense	-		-	-		-		-		-		-			-		- 1		-
Other Expense	-		-	-		-		-		-		-			-		-		-
Interest and Other (net)	\$ 0.2	\$	0.2	\$ 0.2	\$	0.1	\$	0.1	\$	0.6	\$	0.1	\$	(	0.0)	\$	(0.1)	\$	(0.1)
Pre-Tax Income	(61.8)		(14.1)	(15.6)		(16.5)		(18.0)		(64.2)		(80.6)		(8	3.0)		(29.9)		103.2
Income Taxes	-		-	-		-		-		-		-			-		-		15.5
Net Income (GAAP)	(61.8)		(14.1)	(15.6)		(16.5)		(18.0)		(64.2)		(80.6)		(8	3.0)		(29.9)		87.8
EPS (GAAP) (basic)	\$ (4.51)	\$	(0.53)	\$ (0.58)	\$	(0.60)	\$	(0.65)	\$	(2.35)	\$	(2.57)	\$	(2	60)	\$	(0.85)	\$	2.35
EPS (GAAP) (diluted)	\$ (4.51)	\$	(0.53)	\$ (0.58)	\$	(0.60)	\$	(0.65)	\$	(2.35)	\$	(2.57)	\$	(2	<b>60</b> )	\$	(0.85)	\$	2.35
Total of Reconciliation Items	3.0		2.0	2.0		2.0		2.0		8.0		8.0			3.0		8.0		8.0
Net Income (Non-GAAP)	\$ (58.8)	\$	(12.1)	\$ (13.6)	\$	(14.5)	\$	(16.0)	\$	(56.2)	\$	(72.6)	\$	(80	0.0)	\$	(21.9)	\$	95.8
Impact of Adjustments to EPS	0.49		0.07	0.07		0.07		0.07		0.29		0.26		0.	24		0.23		0.22
EPS (Non-GAAP) (basic)	\$ (22.25)	\$	(0.45)	\$ (0.50)	\$	(0.53)	\$	(0.58)	\$	(2.06)	\$	(2.31)	\$	(2	36)	\$	(0.63)	\$	2.56
EPS (Non-GAAP) (diluted)	\$ (22.25)	\$	(0.45)	\$ (0.50)	\$	(0.53)	\$	(0.58)	\$	(2.06)	\$	(2.31)	\$	(2	36)	\$	(0.63)	\$	2.56
Weighted average shares outstanding (basic) Weighted average shares outstanding (diluted)	13.7 13.7		26.9 26.9	27.1 27.1		27.4 27.4		27.7 27.7		27.3 27.3		31.3 31.3			3.8 3.8		35.2 35.2		37.2 37.2

Source: Company reports and BMO Capital Markets

Page 2 February 14, 2013

**BMO Capital Markets** Tesaro





Last Price ( February 13, 2013): \$19.48 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

February 14, 2013 Page 3

<sup>\*</sup> Current EPS is the 4 Quarter Trailing to Q3/2012.
\* Valuation metrics are based on high and low for the fiscal year.
\* Range indicates the valuation range for the period presented above.

BMO Capital Markets Tesaro

#### **Important Disclosures**

#### **Analyst's Certification**

I, Jim Birchenough, M.D., hereby certify that the views expressed in this report accurately reflect my personal views about the subject securities or issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

Analysts who prepared this report are compensated based upon (among other factors) the overall profitability of BMO Capital Markets and their affiliates, which includes the overall profitability of investment banking services. Compensation for research is based on effectiveness in generating new ideas and in communication of ideas to clients, performance of recommendations, accuracy of earnings estimates, and service to clients.

Analysts employed by BMO Nesbitt Burns Inc. and/or BMO Capital Markets Ltd. are not registered as research analysts with FINRA. These analysts may not be associated persons of BMO Capital Markets Corp. and therefore may not be subject to the NASD Rule 2711 and NYSE Rule 472 restrictions on communications with a subject company, public appearances and trading securities held by a research analyst account.

#### **Company Specific Disclosure**

Disclosure 1: BMO Capital Markets has undertaken an underwriting liability with respect to this issuer within the past 12 months.

Disclosure 2: BMO Capital Markets has provided investment banking services with respect to this issuer within the past 12 months.

Disclosure 3: BMO Capital Markets has managed or co-managed a public offering of securities with respect to this issuer within the past 12 months.

Disclosure 4: BMO Capital Markets or an affiliate has received compensation for investment banking services from this issuer within the past 12 months.

Disclosure 6: This issuer is a client (or was a client) of BMO Nesbitt Burns Inc., BMO Capital Markets Corp., BMO CM Ltd. or an affiliate within the past 12 months: Investment Banking Services.

Disclosure 9: BMO Capital Markets makes a market in this security.

#### Methodology and Risks to Our Price Target/Valuation

Methodology: We arrive at our price target by applying a 20x multiple to 2017 GAAP EPS estimate of \$2.35 and discounting 25%.

Risks: There are a number of risks associated with investment in biotechnology companies. These risks include, but are not limited to, risk of clinical trial delay or failure, adverse regulatory decisions including product non-approval, unanticipated adverse effects of drugs which may result in removal from market, risk of manufacturing difficulties, capital market risk which may impair the ability to fund product discovery, research, regulatory filing, manufacture and/or commercialization, risk in attaining and retaining appropriate development or commercial partners, lower-than-expected product adoption, difficulties in gaining appropriate reimbursement for products from payors, unforeseen generic and branded competition, risk to patents being invalidated, and failure to meet earnings and revenue expectations.

Distribution of Ratings (December 31, 2012)

Rating		BMOCM US	BMOCM US	BMOCM US	BMOCM	BMOCM	Starmine
Category	BMO Rating	Universe*	IB Clients**	IB Clients***	Universe****	IB Clients****	Universe
Buy	Outperform	37.0%	17.7%	52.9%	38.5%	50.5%	54.0%
Hold	Market Perform	60.7%	9.6%	47.1%	57.3%	48.4%	40.6%
Sell	Underperform	2.4%	0.0%	0.0%	4.2%	1.0%	5.4%

- Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.
- \*\* Reflects rating distribution of all companies from which BMO Capital Markets Corp. has received compensation for Investment Banking services as percentage within ratings category.
- \*\*\* Reflects rating distribution of all companies from which BMO Capital Markets Corp. has received compensation for Investment Banking services as percentage of Investment Banking clients.
- \*\*\*\* Reflects rating distribution of all companies covered by BMO Capital Markets equity research analysts.
- \*\*\*\*\* Reflects rating distribution of all companies from which BMO Capital Markets has received compensation for Investment Banking services as percentage of Investment Banking clients.

#### **Ratings and Sector Key**

We use the following ratings system definitions:

OP = Outperform - Forecast to outperform the market;

Mkt = Market Perform - Forecast to perform roughly in line with the market;

Und = Underperform - Forecast to underperform the market;

(S) = speculative investment;

NR = No rating at this time;

R = Restricted – Dissemination of research is currently restricted.

Market performance is measured by a benchmark index such as the S&P/TSX Composite Index, S&P 500, Nasdaq Composite, as appropriate for each company. BMO Capital Markets' seven Top 15 lists guide investors to our best ideas according to different objectives (CDN Large Cap, CDN Small Cap, US Large Cap, US Small cap, Income, CDN Quant, and US Quant) have replaced the Top Pick rating.

Page 4 • February 14, 2013

BMO Capital Markets Tesaro

#### **Other Important Disclosures**

For Other Important Disclosures on the stocks discussed in this report, please go to

http://researchglobal.bmocapitalmarkets.com/Public/Company\_Disclosure\_Public.aspx or write to Editorial Department, BMO Capital Markets, 3 Times Square, New York, NY 10036 or Editorial Department, BMO Capital Markets, 1 First Canadian Place, Toronto, Ontario, M5X 1H3.

#### **Prior BMO Capital Markets Ratings Systems**

http://researchglobal.bmocapitalmarkets.com/documents/2009/prior rating systems.pdf

#### **Dissemination of Research**

Our research publications are available via our web site http://www.bmocm.com/research/. Institutional clients may also receive our research via FIRST CALL, FIRST CALL Research Direct, Reuters, Bloomberg, FactSet, Capital IQ, and TheMarkets.com. All of our research is made widely available at the same time to all BMO Capital Markets client groups entitled to our research. Additional dissemination may occur via email or regular mail. Please contact your investment advisor or institutional salesperson for more information.

#### **Conflict Statement**

A general description of how BMO Financial Group identifies and manages conflicts of interest is contained in our public facing policy for managing conflicts of interest in connection with investment research which is available at <a href="http://researchglobal.bmocapitalmarkets.com/Public/Conflict">http://researchglobal.bmocapitalmarkets.com/Public/Conflict</a> Statement Public aspx.

#### **General Disclaimer**

"BMO Capital Markets" is a trade name used by the BMO Investment Banking Group, which includes the wholesale arm of Bank of Montreal and its subsidiaries BMO Nesbitt Burns Inc., BMO Capital Markets Ltd. in the U.K. and BMO Capital Markets Corp. in the U.S. BMO Nesbitt Burns Inc., BMO Capital Markets Ltd. and BMO Capital Markets Corp are affiliates. Bank of Montreal or its subsidiaries ("BMO Financial Group") has lending arrangements with, or provide other remunerated services to, many issuers covered by BMO Capital Markets. The opinions, estimates and projections contained in this report are those of BMO Capital Markets as of the date of this report and are subject to change without notice. BMO Capital Markets endeavours to ensure that the contents have been compiled or derived from sources that we believe are reliable and contain information and opinions that are accurate and complete. However, BMO Capital Markets makes no representation or warranty, express or implied, in respect thereof, takes no responsibility for any errors and omissions contained herein and accepts no liability whatsoever for any loss arising from any use of, or reliance on, this report or its contents. Information may be available to BMO Capital Markets or its affiliates that is not reflected in this report. The information in this report is not intended to be used as the primary basis of investment decisions, and because of individual client objectives, should not be construed as advice designed to meet the particular investment needs of any investor. This material is for information purposes only and is not an offer to sell or the solicitation of an offer to buy any security. BMO Capital Markets or its affiliates will buy from or sell to customers the securities of issuers mentioned in this report on a principal basis, BMO Capital Markets or its affiliates, officers, directors or employees have a long or short position in many of the securities discussed herein, related securities or in options, futures or other derivative instruments based thereon. The reader should assume that BMO Capital Markets or its affiliates may have a conflict of interest and should not rely solely on this report in evaluating whether or not to buy or sell securities of issuers discussed herein.

#### **Additional Matters**

To Canadian Residents: BMO Nesbitt Burns Inc., affiliate of BMO Capital Markets Corp., furnishes this report to Canadian residents and accepts responsibility for the contents herein subject to the terms set out above. Any Canadian person wishing to effect transactions in any of the securities included in this report should do so through BMO Nesbitt Burns Inc.

The following applies if this research was prepared in whole or in part by Andrew Breichmanas, Tony Robson, or Edward Sterck: This research is not prepared subject to Canadian disclosure requirements. This research is prepared by BMO Capital Markets Limited and subject to the regulations of the Financial Services Authority (FSA) in the United Kingdom. FSA regulations require that a firm providing research disclose its ownership interest in the issuer that is the subject of the research if it and its affiliates own 5% or more of the equity of the issuer. Canadian regulations require that a firm providing research disclose its ownership interest in the issuer that is the subject of the research if it and its affiliates own 1% or more of the equity of the issuer that is the subject of the research. Therefore BMO Capital Markets Limited will only disclose its and its' affiliates ownership interest in the subject issuer if such ownership exceeds 5% of the equity of the issuer.

To U.S. Residents: BMO Capital Markets Corp. and/or BMO Nesbitt Burns Securities Ltd., affiliates of BMO NB, furnish this report to U.S. residents and accept responsibility for the contents herein, except to the extent that it refers to securities of Bank of Montreal. Any U.S. person wishing to effect transactions in any security discussed herein should do so through BMO Capital Markets Corp. and/or BMO Nesbitt Burns Securities Ltd.

To U.K. Residents: In the UK this document is published by BMO Capital Markets Limited which is authorised and regulated by the Financial Services Authority. The contents hereof are intended solely for the use of, and may only be issued or passed on to, (I) persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order") or (II) high net worth entities falling within Article 49(2)(a) to (d) of the Order (all such persons together referred to as "relevant persons"). The contents hereof are not intended for the use of and may not be issued or passed on to, retail clients.

Page 5 • February 14, 2013

**BMO Capital Markets Tesaro** 

### ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

BMO Financial Group (NYSE, TSX: BMO) is an integrated financial services provider offering a range of retail banking, wealth management, and investment and corporate banking products. BMO serves Canadian retail clients through BMO Bank of Montreal and BMO Nesbitt Burns. In the United States, personal and commercial banking clients are served by BMO Harris Bank N.A., Member FDIC. Investment and corporate banking services are provided in Canada and the US through BMO Capital Markets.

BMO Capital Markets is a trade name used by BMO Financial Group for the wholesale banking businesses of Bank of Montreal, BMO Harris Bank N.A, BMO Ireland Plc, and Bank of Montreal (China) Co. Ltd. and the institutional broker dealer businesses of BMO Capital Markets Corp. (Member SIPC), BMO Nesbitt Burns Trading Corp. S.A., BMO Nesbitt Burns Securities Limited (Member SIPC) and BMO Capital Markets GKST Inc. (Member SIPC) in the U.S., BMO Nesbitt Burns Inc. (Member Canadian Investor Protection Fund) in Canada, Europe and Asia, BMO Capital Markets Limited in Europe, Asia and Australia and BMO Advisors Private Limited in India.

"Nesbitt Burns" is a registered trademark of BMO Nesbitt Burns Corporation Limited, used under license. "BMO Capital Markets" is a trademark of Bank of Montreal, used under license. "BMO (M-Bar roundel symbol)" is a registered trademark of Bank of Montreal, used under license.

> ® Registered trademark of Bank of Montreal in the United States, Canada and elsewhere. TM Trademark Bank of Montreal

> > ©COPYRIGHT 2013 BMO CAPITAL MARKETS CORP.

A member of **BMO** Financial Group



February 14, 2013 Page 6 •