

Biotechnology

Onconova Therapeutics, Inc.

(ONTX) - NEUTRAL

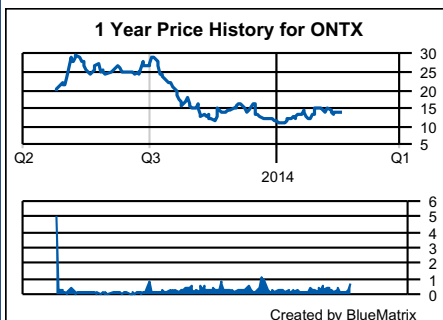
Price: **\$13.86**
Fair Value Estimate: \$10.00
52-Week Range: \$10.80-\$31.13
Market Cap (MM): \$297
Shr.O/S-Diluted (mm): 21.4
Average Daily Volume: 298,763

FYE: Dec	2011A	2012A	2013E
EPS:	--	\$(11.50)A	\$(5.25)E
Prior EPS:	NC		NC
P/E Ratio:	--	NA	NA

Quarterly EPS:			
Q1	--	--	\$(1.03)E
Q2	--	--	\$(5.21)E
Q3	--	--	\$(1.34)E
Q4	--	--	\$(1.02)E

FYE: Dec	2011A	2012A	2013E
Revenue (M):	--	\$46.0A	\$3.9E

Quarterly Revenue (M):			
Q1	--	--	\$1.1E
Q2	--	--	\$0.6E
Q3	--	--	\$1.1E
Q4	--	--	\$1.1E



Equity Research
Note

ONTX: Negative High-Risk MDS Data; Downgrading to Neutral; FV to \$10

INVESTMENT CONCLUSION:

ONTX announced that the Phase III rigosertib study in patients with higher-risk MDS did not meet its primary endpoint of overall survival versus best supportive care (BSC). However, a post-hoc analysis revealed that a subset of patients who had progressed on or failed previous treatments with hypomethylating agents (HMAs) demonstrated a statistically significant increase in median overall survival (OS). The company intends to meet with the FDA as soon as possible to discuss the data and determine the regulatory pathway for rigosertib. Despite the positive subset analysis and lack of therapeutic options, we believe that the FDA will likely require a new Phase III study for approval as the company had a Special Protocol Assessment (SPA) in place and did not meet the primary endpoint. Rightly or wrongly, rigosertib's failure today also casts a shadow on its potential in other indications. For the reasons noted above, we are downgrading ONTX shares to Neutral from Buy and reducing our fair value estimate to \$10 from \$40 based on delayed time to approval and reduction in peak penetration in a smaller subset of MDS patients.

KEY POINTS:

- **Rigosertib missed the primary endpoint. Post-hoc analysis positive in subset of patients. Data from secondary endpoints not disclosed yet.** IV rigosertib plus BSC missed the primary endpoint of improving OS versus BSC alone in the Phase III ONTIME trial to treat myelodysplastic syndromes (MDS) (8.2 months vs. 5.8 months, Hazard Ratio (HR)=0.86, p=0.27). A post-hoc analysis showed rigosertib significantly improved OS vs. BSC in a subset of patients who had progressed on or failed previous treatment with hypomethylating agents (HR=0.67, p=0.022) but did not significantly improve OS vs. BSC in the subset of patients who had relapsed after prior hypomethylating agents (HR and p-value undisclosed). Data from secondary endpoints such as overall response, bone marrow response and hematological improvements were not disclosed but will be presented at the upcoming ASCO conference (May 30-Jun 3; Chicago).
- **Next catalysts.** Key upcoming catalysts include regulatory discussions with the FDA regarding the regulatory pathway in higher-risk MDS patients (1H), ONTIME data presentation at ASCO, completion of two Phase II lower-risk MDS studies (3Q) and regulatory discussions in lower-risk population (4Q).
- **Downgrading to Neutral and lowering fair value estimate to \$10 from \$40.** We suggest staying on the sidelines until we gain clarity on the development and regulatory pathway in the higher- and lower-risk MDS population. Our revised fair value estimate is a result of delayed time to approval and lowered peak penetration in a smaller subset of patients.

Research Analyst Certifications and Important Disclosures
are on pages 2 - 3 of this report

IMPORTANT DISCLOSURES

Research Analyst Certification

I, Kimberly Lee, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

Onconova Therapeutics, Inc. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

Janney Montgomery Scott LLC currently acts as a market-maker in the securities of Onconova Therapeutics, Inc..

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Onconova Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Onconova Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Onconova Therapeutics, Inc. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

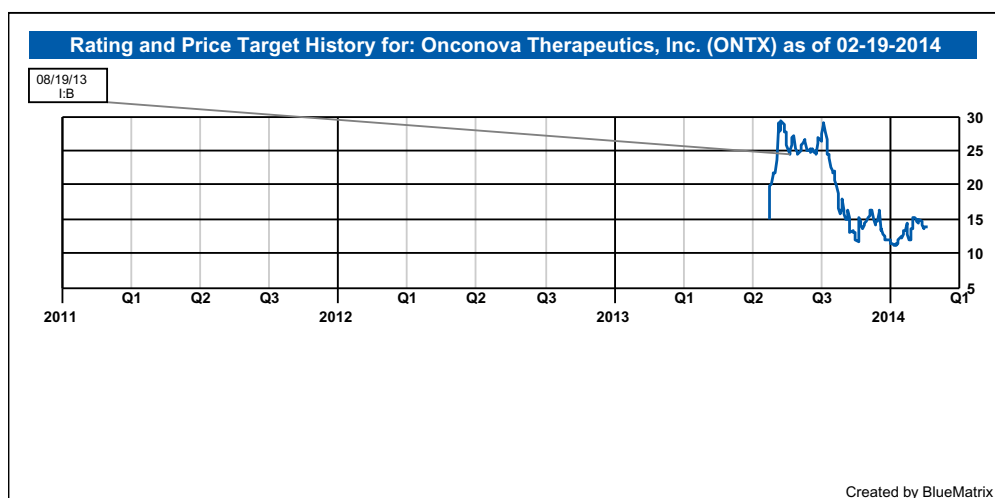
Definition of Ratings

BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

NEUTRAL: Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

SELL: Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

Price Charts



Janney Montgomery Scott Ratings Distribution as of 12/31/13

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	247	53.00	30	12.10
NEUTRAL [N]	211	45.50	13	6.20
SELL [S]	7	1.50	0	0.00

***Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.**

Other Disclosures

Janney Montgomery Scott LLC, is a U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the New York Stock Exchange, the Financial Industry Regulatory Authority and the Securities Investor Protection Corp.

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