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Onconova Therapeutics, Inc.

**ONTX - NEUTRAL** 

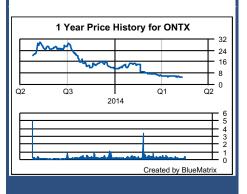
May 13, 2014

#### **Biotechnology**

# Onconova Therapeutics, Inc.

#### (ONTX) - NEUTRAL

Price: Fair Value Esti 52-Week Rang Market Cap (M Shr.O/S-Dilute Average Daily	e: IM): ed (mm):	\$5.32 \$10.00 \$5.25-\$31.13 \$115 21.6 347,752					
FYE: Dec EPS: Prior EPS: P/E:	2011A  NC 	2012A \$(11.50)A NA					
Quarterly EPS: Q1 Q2 Q3 Q4	   	  	\$(1.03)E \$(5.21)E \$(1.34)E \$(0.68)E				
FYE: Dec Revenue (M):		2012A \$46.0A					
Quarterly Reve Q1 Q2 Q3 Q4	enue (M):   	  	\$1.1E \$0.6E \$1.1E \$1.1E				



Equity Research
FLASH Note

### ONTX: Await Clarity on the MDS Programs

#### **KEY POINTS:**

- Can rigosertib be approved in a subset of higher-risk MDS patients? The company anticipates having regulatory discussions with the FDA and EMA in 2Q and 3Q, respectively, to determine next steps. Based on the ONTIME data which demonstrated an increase in survival of 3.9 months (HR=0.66; p-value =0.017) in a subset of patients with primary HMA failure, the company may consider filing for approval in this patient population. An ongoing Phase IIIB study in patients who have progressed on HMAs should provide additional tolerability and activity data in post-HMA MDS patients. It remains to be seen whether or not rigosertib could be approved in a subset of patients as the FDA usually does not favor post-hoc subset analyses unless the analyses were pre-specified.
- Advancement of lower-risk MDS program in 2H. The company intends to initiate a Phase III double-blind, placebo-controlled study under an SPA in 2H, pending full discussions with the EMA. The company has an ongoing study to examine the utility of a prognostic genomic methylation marker for transfusion-dependent lower-risk MDS patients to help distinguish between responders and non-responders. This marker will be used in future studies but the question remains whether or not the marker will be used to preselect patients for the Phase III study or to provide additional stratification or subset data. Lastly, ONTX has initiated a Phase I/II rigosertib plus azacitidine (Vidaza) study in front-line MDS patients. The company has completed the first two dosing cohort in the dose escalation stage. Once the final dose is selected, the company will initiate the Phase II portion of the study in the U.S. and Europe and report data in 2H.
- Cash inflows needed by 2Q15. The company ended 1Q with approximately \$84.6 million in cash and equivalents, which is enough to sustain operations through 2Q15, per our estimates.
- Our outlook remains neutral. Reiterate \$10 fair value estimate. We suggest staying on the sidelines until we gain clarity on the development and regulatory pathways in the higher- and lower-risk MDS population. Our fair value estimate is based on a DCF analysis of cash flows through 2021.

Research Analyst Certifications and Important Disclosures are on pages 3 - 4 of this report

### Onconova Therapeutics (NASDAQ: ONTX) Income Statement

(In thousands, except per share data)

				For the Quarter Ending				For the Quarter Ending									
	20	011 A	2012 A	3/31/1	ВА	6/30/13 A	9/30/13		12/31/13 A	201	13 A	3/31/14 A	6/30/14 E	9/30/14 E	12/3	31/14 E	2014 E
Revenue: Product Revenue	\$	_	\$ -	\$		\$ -	\$	- \$		\$	_	\$ -	\$ -		- \$	_	\$ -
Collaboration Revenue Grant Revenue	•	227 1,260	45,993 197		,116 -	591 -	*	116 -	1,930		4,753 -	447	113	11:		113 -	786 -
Total Revenue		1,487	46,190	1	,116	591	1,	116	1,930		4,753	447	113	11:	3	113	786
Cost of Product Sales Gross Profit		1,487	46,190	1	<u>-</u> ,116	<u>-</u> 591	1,	<u>-</u> 116	1,930		4,753	447	113	11:	<u>-</u>	113	786
Cost and Expenses: Research and Development General and Administrative		22,624 6,436	52,762 15,707		,756 ,346	10,047 3,117	15,2 5.9	293 927	12,086 4,403		50,182 16,793	14,248 4,932	15,530 5,129	16,92 5,33		18,452 5,548	65,158 20,944
Total Costs and Expenses		29,060	68,469	-	102	13,164	21,2		16,489		66,975	19,180	20,660	22,26		23,999	86,102
Operating Income (Loss)		(27,573)	(22,279)		,986)	(12,573)	(20,		(14,559)		62,222)	(18,733)	(20,547)	(22,15		(23,886)	(85,316)
Other Income (Expense): Interest Income (Expense) Other		(19) 1,298	(8,608) 975		- 141	(2) 13		(1) 16	(1) (65)		(4) 105	16 38	24	1	8 <u>-</u>	11 <u>-</u>	84 38
Loss Before Income Taxes Income Taxes		(26,294)	(29,912)	(14	,845) <u>-</u>	(12,562)	(20,0	089) 432	(14,625) 3	(	62,121) 435	(18,679)	(19,049)	(20,53	3) <u>-</u>	(22,152)	(78,816)
Net Income Less: Accretion of Redeemable Convertible Preferred		(26,294) (4,020)	(29,912) (3,953)		,845) ,019)	(12,562) (1,032)	(20,5	521) 269)	(14,628) 13		(62,556) (2,307)	(18,679)	(19,049)	(20,53	3) <u>-</u>	(22,152)	(78,816)
Net Income Applicable to Common Stockholders	\$	(30,314)	\$ (33,865)	\$ (15	,864)	\$ (13,594)	\$ (20,	790) \$	(14,615)	\$ (	64,863)	\$ (18,679)	\$ (19,049)	\$ (20,53	3) \$	(22,152)	\$ (78,816)
Basic Earnings Per Share Diluted Earnings Per Share	\$		\$ (11.51) \$ (11.51)		1.03) 1.03)			.34) \$ .34) \$			(4.72) (4.72)				5) \$ 5) \$	(1.02) (1.02)	\$ (3.64) \$ (3.64)
Basic Shares Outstanding Diluted Shares Outstanding		2,849 2,849	2,942 2,942		,448 ,448	2,609 2,609	15,4 15,4		21,419 21,419		13,739 13,739	21,568 21,568	21,668 21,619	21,76 21,71		21,868 21,819	21,718 21,669
Effective Tax Rate		0.0%	0.0%		0.0%	0.0%	-2	.2%	0.0%		-0.7%	0.0%	0.0%	0.0	%	0.0%	0.0%
EBITDA Calculation:																	
Loss Before Income Taxes Less: Interest Income	\$	(26,294) 19	\$ (29,912) 8,608	\$ (14	,845)	\$ (12,562) 2	\$ (20,0	089) \$ 1	(14,625)	\$ (	62,121)	\$ (18,679) (16)	\$ (19,049) (24)			(22,152) (11)	\$ (78,816) (84)
Plus: Depreciation & Amortization		316	319		98	109		70	70		347	69	(24) 66	6:		60	(64) 257
EBITDA	\$	(25,959)	\$ (20,985)	\$ (14		\$ (12,451)	\$ (20,0	018) \$	(14,554)	\$ (	61,770)	\$ (18,626)	\$ (19,008)	-		(22,103)	\$ (78,643)
Margins:																	
Gross		100.0%	100.0%	10	0.0%	100.0%	100	.0%	100.0%		100.0%	100.0%	100.0%	100.0	%	100.0%	100.0%
Operating		N/M	N/M		N/M	N/M		N/M	N/M		N/M	N/M	N/M	N/		N/M	N/M
Net Income (Loss)		N/M	N/M		N/M	N/M		N/M	N/M		N/M	N/M	N/M	N/		N/M	N/M
EBITDA		N/M	N/M	-	N/M	N/M		N/M	N/M		N/M	N/M	N/M	N/	IVÍ	N/M	N/M
Year-over-year Growth:			2000.004	10	2.60/	054.007	07	10/	40.407		00.70/	E0.00/	00.004	00.0	2/	04.40/	00.50/
Total Revenue Operating Income			3006.3% N/M	46	3.6% N/M	354.6% -9771.5%		.4%	-40.1% -552.1%		-89.7% N/M	-59.9% N/M	-80.9% N/M	-89.9' N/		-94.1% N/M	-83.5% N/M
Net Income (Loss)			N/M		N/M	-10556.9%	-147		-553.9%		N/M	N/M	N/M	N/		N/M	N/M
Research and Development Expense			133.2%	5	1.0%	N/M		N/M	N/M		-4.9%	11.7%	54.6%	10.7		52.7%	29.8%
General and Administrative Expense			144.0%		6.0%	N/M		N/M	N/M	<u> </u>	6.9%	47.4%	64.6%	-10.0		26.0%	24.7%

Source: Company reports and Janney Montgomery Scott LLC estimates

#### 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.

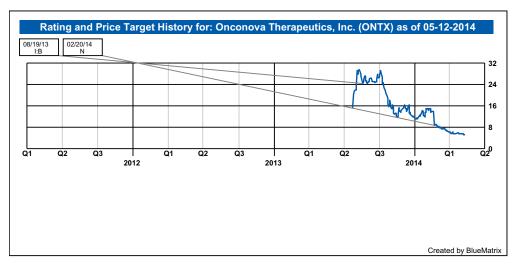
#### **Definition of Ratings**

**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 3/31/14

IB Serv./Past 12 Mos.

Rating	Count	Percent	Count	Percent
BUY [B]	218	51.12	44	20.18
NEUTRAL [N]	205	48.12	21	10.24
SELL [S]	3	0.70	0	0.00

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

#### **Other Disclosures**

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