

Onconova Therapeutics, Inc. (ONTX)

Neutral

Lead Indication Failure Raises Doubts on Rigo, Lowering to Neutral

CONCLUSION

Onconova announced today that rigosertib (rigo) failed to meet its primary endpoint in high-risk MDS, despite a numerical survival benefit for the rigo arm. We are surprised by the result and are introducing a "probability of success" of 25% to our valuation (Exhibits 1 and 2), resulting in a \$9 price target (from \$38) and a Neutral rating. While a subgroup of previous SOC non-responders appeared to perform better, achieving a stat sig improvement in survival, we are wary of post-hoc subset analyses and believe that clarity from FDA on this analyses will not be forthcoming soon. Although oral Rigo continues forward with low-risk MDS, and the company plans to start Phase III "as soon as possible" we expect investors will need to see strong clinical progress for enhanced conviction in the platform.

- **Need greater visibility on partner and FDA views.** While the headline results are clearly disappointing, we are more cautious due to uncertainty on the FDA's thoughts as well as those of partners Baxter and SynBio. For example, Baxter would owe milestones of \$25mn each for joint decisions to pursue additional indications, and we believe these could be at risk considering this failure in MDS and the recent pancreatic cancer failure. Additionally, although a numerical survival benefit was seen, and the subgroup of previously exposed and non-responding patients to hypomethylating agents (SOC) showed enhanced benefit, we believe the FDA is unlikely to give a pass on another trial since this result was not clearly yielded by a prespecified analysis in the SPA-backed trial.
- **ONTIME study, but not a winner.** The Phase III of Rigo in high-risk MDS enrolled 299 patients and randomized 199 to the rigo + best supportive care (BSC) arm. Median OS was 8.2 months for rigo vs. 5.8 mos. for BSC alone. The resulting hazard ratio was 0.86 and p-value of 0.27. In the 184 patients failed or progressed on 1st-line hypomethylator treatment, mOS for rigo was 8.5 mos vs. 4.7 mos for BSC alone. This population may indeed make a valid population for future studies, however this will require feedback from the FDA, EMA, and partners, and we await the outcome of these discussions from the sidelines for now.

RISKS TO ACHIEVEMENT OF PRICE TARGET

Principal risks include 1) failure of rigosertib to differentiate itself in clinical trials, 2) delay of rigosertib in reaching the market, 3) increased competition from similar drugs in development.

COMPANY DESCRIPTION

Onconova focuses on cancer and radiation injury therapies

PRICE: US\$13.86

Note: price is as of the close Feb. 19, 2014

TARGET: US\$9.00

DCF of projected free cash flows for 2015-2026, with a 10% discount rate, 25% probability of success

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Changes	Previous	Current
Rating	Overweight	Neutral
Price Tgt	US\$38.00	US\$9.00
FY13E Rev (mil)	—	US\$3.8
FY14E Rev (mil)	—	US\$104.0
FY13E EPS	—	US\$(6.63)
FY14E EPS	—	US\$0.91
52-Week High / Low	US\$31.13 / US\$10.80	
Shares Out (mil)	20.8	
Market Cap. (mil)	US\$288.3	
Avg Daily Vol (ooo)	299	
Book Value/Share	US\$0.85	
Net Cash Per Share	US\$3.33	
Debt to Total Capital	0%	
Yield	0.00%	
Fiscal Year End	Dec	

Price Performance - 1 Year



Source: Bloomberg

YEAR	REVENUE (US\$ m)						EARNINGS PER SHARE (US\$)					
	Mar	Jun	Sep	Dec	FY	FY RM	Mar	Jun	Sep	Dec	FY	FY P/E
2012A	—	—	—	—	46.2	6.2x	—	—	—	—	(15.35)	NM
2013E	1.1A	0.6A	1.1A	1.0	3.8	75.9x	(5.69)A	(4.81)A	(1.33)A	(1.02)	(6.63)	NM
2014E	51.0	51.0	1.0	1.0	104.0	2.8x	1.49	1.46	(1.00)	(1.04)	0.91	15.2x

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Exhibit 1

CURRENT ONCONOVA VALUATION

<i>Assumed Discount Rate (%)</i>	10.0%
Discounted Net Cash Flow (2015-26)	\$659,514
<i>Terminal Growth Rate (%)</i>	No TV
<i>Implied Terminal Year FCF Multiple</i>	0.0x
Present Value of Terminal Value	\$0
<i>Terminal Value as % of total</i>	0.0%
Enterprise Value	\$659,514
Add: Net Cash	114,836
Equity Value	\$774,350
Shares Outstanding 2014E (million)	20,614
Equity Value per Share	\$37.56
<i>Probability of success</i>	25.0%
Probability-weighted value per share	\$9.39

Source: Piper Jaffray

Exhibit 2

PRIOR ONCONOVA VALUATION

<i>Assumed Discount Rate (%)</i>	10.0%
Discounted Net Cash Flow (2015-26)	\$659,514
<i>Terminal Growth Rate (%)</i>	No TV
<i>Implied Terminal Year FCF Multiple</i>	0.0x
Present Value of Terminal Value	\$0
<i>Terminal Value as % of total</i>	0.0%
Enterprise Value	\$659,514
Add: Net Cash	114,836
Equity Value	\$774,350
Shares Outstanding 2014E (million)	20,614
Equity Value per Share	\$37.56

Source: Piper Jaffray

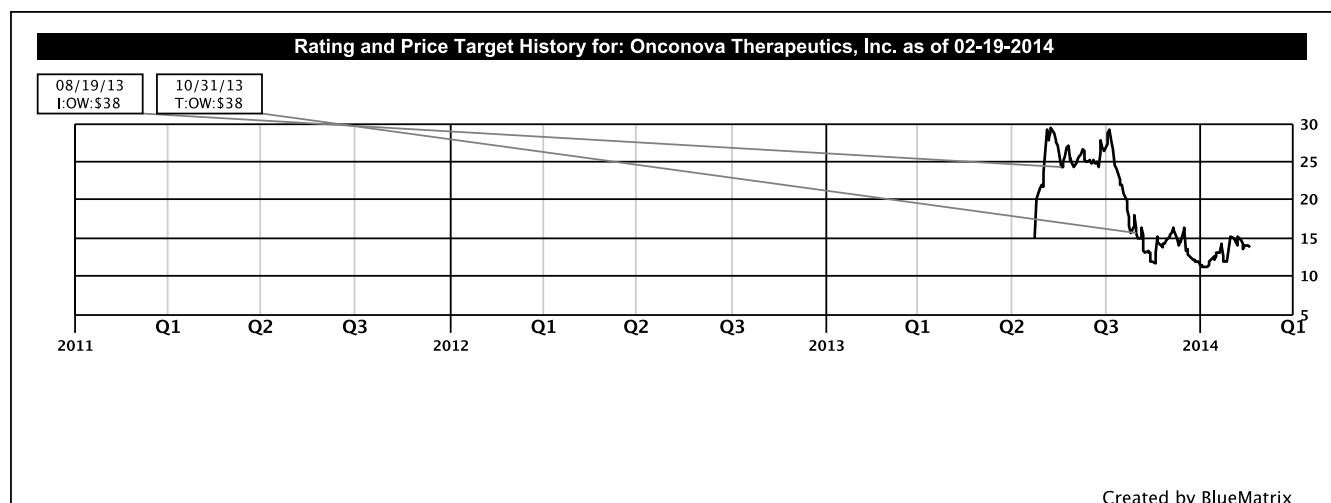
Onconova Earnings Model	2012A	1Q 13A	2Q 13A	3Q 13A	4Q 13E	2013E	1Q 14E	2Q 14E	3Q 14E	4Q 14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
(\$ in thousands, except per share amounts)																							
US Rigosertib Sales	0	0	0	0	0	0	0	0	0	0	0	21,930	82,400	152,317	228,856	311,675	390,362	452,161	522,121	581,562	632,689	670,246	709,534
Int Rigosertib Sales	0	0	0	0	0	0	0	0	0	0	0	0	55,587	127,572	187,431	239,444	321,632	369,073	426,819	473,666	515,704	560,140	598,755
Total Rigosertib Sales	0	0	0	0	0	0	0	0	0	0	0	21,930	137,987	279,889	416,287	551,119	711,994	821,234	948,939	1,055,228	1,148,393	1,230,386	1,308,289
US Rigosertib Sales	0	0	0	0	0	0	0	0	0	0	0	21,930	82,400	152,317	228,856	311,675	390,362	452,161	522,121	581,562	632,689	670,246	709,534
Ex-US Royalty	0	0	0	0	0	0	0	0	0	0	0	0	7,782	22,963	37,486	52,678	77,192	95,959	110,973	123,153	134,083	145,636	155,676
License and milestone revenues	0	0	0	0	0	0	50,000	50,000	50,000	50,000	100,000	100,000	50,000	50,000	100,000	0	0	0	0	0	0	0	0
Collaboration R&D revenues	1,116	591	1,116	1,000	3,823	1,000	1,000	1,000	1,000	1,000	4,000	4,000	4,000	3,000	0	0	0	0	0	0	0	0	0
Total Revenues	46,190	1,116	591	1,116	1,000	3,823	51,000	51,000	1,000	1,000	104,000	125,930	144,182	228,280	366,342	364,353	467,553	548,120	633,094	704,715	766,772	815,883	865,210
Costs & Expenses:																							
Cost of Goods Sold	0	0	0	0	0	0	0	0	0	0	0	2,193	14,008	25,894	37,761	49,868	62,458	67,824	78,318	87,234	94,903	100,537	106,430
R&D	52,762	12,756	10,047	15,293	16,058	54,154	14,452	15,036	15,788	16,577	61,852	80,408	92,469	101,716	110,361	115,880	121,673	127,757	134,145	140,852	147,895	155,290	163,054
SG&A	15,707	3,346	3,117	5,927	6,046	18,436	6,046	6,046	6,046	6,046	24,182	45,146	63,204	75,845	87,222	97,689	107,457	116,054	123,017	129,168	135,626	142,408	149,528
Total Operating Expenses	68,469	16,102	13,164	21,220	22,103	72,589	20,497	21,081	21,833	22,622	86,034	127,747	169,681	203,455	235,345	263,436	291,589	311,635	335,480	357,255	378,425	398,234	419,012
Operating Income	(22,279)	(14,986)	(12,573)	(20,104)	(21,103)	(68,766)	30,503	29,919	(20,833)	(21,622)	17,966	(1,817)	(25,499)	24,825	130,998	100,917	175,965	236,485	297,613	347,461	388,347	417,648	446,198
Interest and Other Income (Expense), net	(7,633)	141	11	15	175	342	146	193	238	206	783	919	1,168	896	1,048	1,999	2,650	3,812	5,307	7,189	9,366	11,827	14,499
Pretax Income (Loss)	(29,912)	(14,845)	(12,562)	(20,089)	(20,928)	(68,424)	30,649	30,111	(20,595)	(21,416)	18,749	(898)	(24,331)	25,721	132,046	102,916	178,615	240,296	302,921	354,649	397,713	429,475	460,696
Income Expense (Benefit)	0	0	0	432	0	0	0	0	0	0	0	(45)	(1,825)	3,858	26,409	25,729	53,584	84,104	106,022	124,127	139,200	150,316	161,244
Tax Rate	0.0%	0.0%	0.0%	-2.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	5.0%	7.5%	15.0%	20.0%	25.0%	30.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%
Other (Accr of preferred stock)	(3,953)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Net Income (Loss) GAAP	(33,865)	(14,845)	(12,562)	(20,521)	(20,928)	(68,424)	30,649	30,111	(20,595)	(21,416)	18,749	(853)	(22,506)	21,863	105,637	77,187	125,030	156,192	196,898	230,522	258,514	279,159	299,453
Stock option expense	0	600	(1,032)	613	600	781	600	600	600	600	2,400	2,508	2,686	2,715	2,811	2,899	2,976	3,040	3,344	3,678	4,046	4,451	4,896
Other	2,978	(141)	0	(16)	0	(157)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Net Income (Loss) Non-GAAP	(30,887)	(14,386)	(13,594)	(19,924)	(20,328)	(67,800)	31,249	30,711	(19,995)	(20,816)	21,149	1,655	(19,820)	24,578	108,448	80,086	128,006	156,192	196,898	230,522	258,514	279,159	299,453
Diluted Earnings Per Share Non-GAAP	(\$14.00)	(\$5.52)	(\$5.21)	(\$1.29)	(\$0.99)	(\$6.56)	\$1.52	\$1.49	(\$0.97)	(\$1.01)	\$1.03	\$0.08	(\$0.87)	\$1.03	\$4.33	\$3.04	\$4.63	\$5.38	\$6.46	\$7.21	\$7.70	\$7.92	\$8.09
Basic Earnings Per Share Non-GAAP	(\$14.00)	(\$5.52)	(\$5.21)	(\$1.29)	(\$0.99)	(\$6.56)	\$1.52	\$1.49	(\$0.97)	(\$1.01)	\$1.03	\$0.08	(\$0.87)	\$1.03	\$4.33	\$3.04	\$4.63	\$5.38	\$6.46	\$7.21	\$7.70	\$7.92	\$8.09
Diluted Earnings Per Share GAAP	(\$15.35)	(\$5.69)	(\$4.81)	(\$1.33)	(\$1.02)	(\$6.63)	\$1.49	\$1.46	(\$1.00)	(\$1.04)	\$0.91	(\$0.04)	(\$0.99)	\$0.92	\$4.22	\$2.93	\$4.53	\$5.38	\$6.46	\$7.21	\$7.70	\$7.92	\$8.09
Basic Earnings Per Share GAAP	(\$15.35)	(\$5.69)	(\$4.81)	(\$1.33)	(\$1.02)	(\$6.63)	\$1.49	\$1.46	(\$1.00)	(\$1.04)	\$0.91	(\$0.04)	(\$0.99)	\$0.92	\$4.22	\$2.93	\$4.53	\$5.38	\$6.46	\$7.21	\$7.70	\$7.92	\$8.09
Diluted Shares Outstanding (th)	2,207	2,607	2,609	15,480	20,614	10,328	20,614	20,614	20,614	20,614	20,614	21,645	22,727	23,864	25,057	26,310	27,625	29,006	30,457	31,980	33,578	35,257	37,020
Basic Shares Outstanding (th)	2,207	2,607	2,609	15,480	20,614	10,328	20,614	20,614	20,614	20,614	20,614	21,645	22,727	23,864	25,057	26,310	27,625	29,006	30,457	31,980	33,578	35,257	37,020

Proprietary to Piper Jaffray & Co. February 19, 2014

ONTX: Charles Duncan; 212-284-5025

Current disclosure information for this company can be found at <http://www.piperjaffray.com/researchdisclosures>.

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			Count	Percent
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