

Onconova Therapeutics, Inc. (ONTX)

Overweight

KOL Commentary Suggests Rigo' is a Pipeline in a Product

CONCLUSION

Onconova held an Analyst day today covering the development history and plans for lead candidate rigosertib. Expectations for the pivotal data in int-2/high risk MDS remained consistent for data sometime in 1Q14 (we expect early in the quarter). We remain encouraged based on rigo's prior activity in the clinic, its good safety profile, and KOL feedback on the program. The review of rigo' was comprehensive and pointed to the drug's mechanism of action and future development directions, which enhance our conviction that rigo' could become a "pipeline in a product," rather than "just" a candidate in MDS. Supportive of this view was new data describing inhibition of Ras (through Raf) by rigo'. Ras has been a very difficult target, yet at the same time is a key oncogene; this suggests new avenues for investigating broadened utility for rigo'. We reiterate our Overweight rating and \$38 price target on Onconova.

- **Expectations in int-2/high risk MDS - waiting for the data.** The presenting KOLs pointed out that the current standard of care, azacitidine, has minimal impact on survival in this setting. They highlighted a large (400-500 pt.) study conducted at Hopkins that found a median 5.6 months survival. The presenter also believes that a 10-13 week benefit in survival is clinically meaningful. This range of benefit is what the ongoing Phase III for rigo' is powered to show based on the prior Phase I and Phase II results for the drug. Given the lack of effective treatments, if the Phase III for rigo' is successful and it is approved, we anticipate a rapid inclusion of the drug in the treatment algorithm by clinicians. Note that success in the Phase III study provides for a \$50mn milestone from Baxter and an additional \$25mn is available for filing in high-risk MDS.
- **The need for new options.** Investigator Dr. Raza from Columbia emphasized the need for multiple treatment options that can enable sequential treatments, which may address acquired or emergent resistance. Also, the KOLs assert that better identification of key disease-driving biomarkers is essential for progress in MDS (and cancer in general). We believe this progress is being made, evidenced in part through the meaningful investigations of molecular markers indicating response to rigo' in lower risk MDS patients presented by Dr. Raza and Onconova at ASH. We expect the company to continue to investigate the relationship between specific markers and treatment benefit and anticipate important developments in the coming years. MDS/AML (and other myeloid diseases) should be an exciting and rapidly evolving space for the foreseeable future, in our view, and we expect rigo' to take part in defining novel treatment paradigms.

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

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	6.0x	—	—	—	—	(15.35)	NM
2013E	1.1A	0.6A	1.1A	1.0	3.8	72.9x	(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	2.7x	1.49	1.46	(1.00)	(1.04)	0.91	14.6x

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Onconova Therapeutics, Inc.

PRICE: US\$13.32

TARGET: US\$38.00

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

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Changes	Previous	Current
Rating	—	Overweight
Price Tgt	—	US\$38.00
FY13E Rev (mil)	—	US\$3.8
FY14E Rev (mil)	—	US\$104.0
FY13E EPS	—	US\$(6.63)
FY14E EPS	US\$1.30	US\$0.91
52-Week High / Low	US\$31.13 / US\$11.73	
Shares Out (mil)	20.8	
Market Cap. (mil)	US\$277.1	
Avg Daily Vol (ooo)	258	
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

Data intensive presentation on combinations of azacitidine with other agents. This presentation largely focused on HDAC inhibitors like vorinostat, other agents such as Revlimid, and generally highlighted interest and activity in finding effective agents for patients. A review of the design and results from the Phase I/II study of the combo of rigo' and azacitidine in MDS/AML emphasized the strong efficacy results for rigo' on par with the best of the other agents being studied. The Phase II portion of the 09-08 combination study is to start next year. The study is currently in the Phase I dose determination phase. Dr. Silverman speculated that smoldering AML may be an interesting indication for examination of the combination as well. This too is a rapidly evolving space (i.e. combination therapy in MDS/AML), a view supported by the KOL commentary, with impressive response rates for some combinations in early studies and many avenues for investigation remaining. We look forward to further study and important pivotal studies in the years to come.

Other thoughts. One point that was raised multiple times at the meeting was a possible comparison to Boehringer Ingelheim's PLK1 inhibitor volasertib. Management pointed out that rigo', based on the new Ras inhibition data, is not a direct and specific PLK inhibitor as is volasertib, but indirectly inhibits PLK1 likely through its actions on Ras. This is further indicated by the lack of myelosuppression by rigosertib while it is a prominent side effect of volasertib.

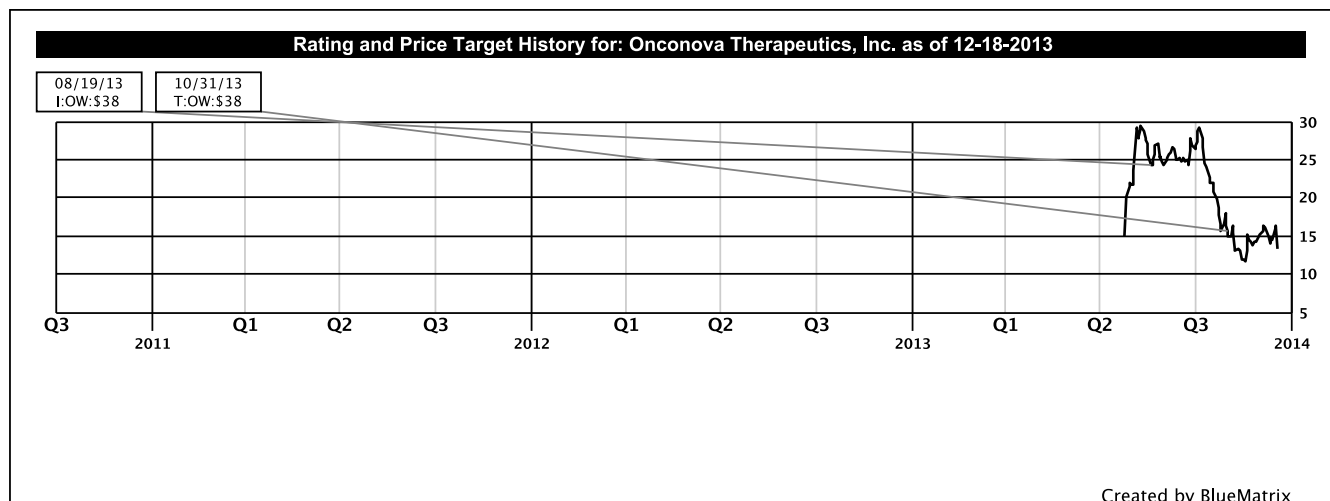
Onconova Earnings Model	2012A	1Q 13A	2Q 13A	3Q 13A	4Q 13E	2013E	1Q 14E	2Q 14E	3Q 14E	4Q 14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
(\$ in thousands, except per share amounts)																							
US Rigosertib Sales	0	0	0	0	0	0	0	0	0	0	0	21,930	82,400	152,317	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. December 19, 2013

ONTX: Charles Duncan; 212-284-5025

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S: Suspending Coverage
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N: Neutral
UW: Underweight
NA: Not Available
UR: Under Review

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			Count	Percent
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Analyst Certification — Charles C. Duncan, PhD, Sr. Research Analyst — Roy Buchanan, Ph.D., Research Analyst

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