Onconova Therapeutics, Inc. (ONTX) — Overweight

ASH Presentations and Near-Term Phase III Set up an Eventful 2014

CONCLUSION

ASH abstracts out today for rigosertib update the Phase II in lower risk MDS (abstract #2745) and summarize prior Phase I/II data in high risk and AML patients (abstract #1527) looking at possible predictive patient characteristics. The Phase II lower risk update includes an additional 19 patients that demonstrated that the response rate (45% rate of transfusion independence in the 8-weeks-plus intermittent treatment group, now 33 patients vs. 15 at ASCO) held up better than we anticipated, and we note a trend to better responses in patients treated with the intermittent schedule. Three of the patients are del5Q mutants, whereas none were in the ASCO data. We look forward to the data presentations at ASH to further our diligence on the potential for rigosertib in the different patient populations and the impact of dosing modifications. We are reiterating our Overweight rating and $38 price target on Onconova.

- **Phase II update supports rigosertib clinical benefit, in our view.** As mentioned above, the response rate in patients on intermittent dosing schedule (2 out of 3 weeks) treated for at least 8 weeks (N=33) indicated that 45% (N=15) of patients achieved transfusion independence. For the entire enrolled ITT population (N=48), a still impressive, in our view, response rate of 35% (N=17) was reported. Also, of the 15 responding patients, 12 were refractory to erythropoiesis stimulating agents (ESAs). Onconova believes the responses in ESA refractory patients may suggest that rigosertib exhibits synergy with those agents as 14 of the 15 responders received concomitant ESAs. We will be curious of how many of the non-responders received ESAs. Also, we wonder if the drug may be useful in reducing ESA use and what a minimal effective dose may be in this setting.

- **Urinary safety details important.** Possibly more important in the presentation at ASH could be the effect of various dose and other management tools to address the urinary side effects of rigosertib. Of the 48 patients, 6 (12.5%) had reversible grade 3 urinary toxicity and 17 had grade 2 (35.4%). It will be interesting to see which dose modifications (560mg morning, 280mg afternoon) or other management techniques have the most impact and which patients responded.

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, including Celgene's oral Vidaza and Astex Pharmaceuticals' SGI-110.

COMPANY DESCRIPTION

Onconova focuses on cancer and radiation injury therapies

PRICE: US$15.35
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$3.7
FY14E Rev (mil)	—	US$104.0
FY13E EPS	—	US$(3.92)
FY14E EPS	—	US$1.08

52-Week High / Low	US$31.13 / US$14.53
Shares Out (mil)	20.8
Market Cap. (mil)	US$319.3
Avg Daily Vol (000)	163
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	6.9x	—	—	—	—	(15.35)	NM
2013E	1.1A	0.6A	1.0	1.0	3.7	86.3x	(5.69)A	(4.81)A	(0.52)	(0.53)	(3.92)	NM
2014E	—	—	—	—	104.0	3.1x	—	—	—	—	1.08	14.2x

DNA methylation status of responders could support companion diagnostic or mechanistic understanding. Onconova indicates in the abstract that hypermethylation of certain genes was associated with responders. This is interesting, we believe, because Vidaza and Dacogen, both approved for MDS, cause hypomethylation of DNA (i.e., the opposite effect that rigosertib is displaying). This supports, from a mechanistic viewpoint, that rigosertib could be effective in Vidaza/Dacogen relapsed/refractory patients, we believe. Top-line survival data from the Phase III study of rigosertib in 2nd-line higher-risk MDS patients are expected by YE13 or early in 2014. These results could also lead to the development and use of a companion diagnostic for rigosertib.

High risk responder subgroups. The other abstract (#1527) describes investigation of possible responding subgroup defining variables from prior studies in higher-risk MDS patients. While the data is limited by a small number of patients, it may help define what to look for in future studies, we believe. Not too surprisingly, in our view, patients with <20% blasts at enrollment were more likely to respond. Age, cytogenetics, or prior responses were not indicative of response to rigosertib. Cystitis may indicate responders and the company intends to investigate further.

Onconova Earnings Model	2012A	1Q 13A	2Q 13A	3Q 13E	4Q 13E	2013E	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	21,930	82,400	152,317	228,856	311,675	390,362	452,161	522,121	581,562	632,689	670,246	709,534
Intl Rigosertib Sales		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**	**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	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	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	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	1,000	1,000	3,707	4,000	4,000	4,000	3,000	0	0	0	0	0	0	0	0	0
Total Revenues	**46,190**	**1,116**	**591**	**1,000**	**1,000**	**3,707**	**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	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	10,549	11,077	44,429	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	3,179	3,243	12,885	15,170	32,980	46,171	55,406	63,716	71,362	78,499	84,778	89,865	94,358	99,076	104,030	109,232
Total Operating Expenses	68,469	16,102	13,164	13,729	14,320	57,314	77,022	115,580	152,648	183,015	211,839	237,110	262,630	280,360	302,328	322,445	341,875	359,857	378,716
Operating Income	**(22,279)**	**(14,986)**	**(12,573)**	**(12,729)**	**(13,320)**	**(53,607)**	**26,978**	**10,350**	**(8,466)**	**45,265**	**154,503**	**127,243**	**204,923**	**267,760**	**330,765**	**382,270**	**424,897**	**456,026**	**486,494**
Interest and Other Income (Expense), net	(7,633)	141	11	77	169	398	707	1,038	1,482	1,392	1,772	2,979	3,921	5,401	7,225	9,449	11,986	14,823	17,890
Pretax Income (Loss)	**(29,912)**	**(14,845)**	**(12,562)**	**(12,652)**	**(13,151)**	**(53,209)**	**27,685**	**11,387**	**(6,984)**	**46,656**	**156,275**	**130,222**	**208,844**	**273,161**	**337,990**	**391,720**	**436,883**	**470,849**	**504,384**
Income Expense (Benefit)	0	0	0	0	0	0	0	569	(524)	6,998	31,255	32,556	62,653	95,606	118,296	137,102	152,909	164,797	176,534
Tax Rate	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														
Net Income (Loss) GAAP	**(33,865)**	**(14,845)**	**(12,562)**	**(12,652)**	**(13,151)**	**(53,209)**	**27,685**	**10,818**	**(6,461)**	**39,658**	**125,020**	**97,667**	**146,191**	**177,555**	**219,693**	**254,618**	**283,974**	**306,052**	**327,850**
Stock option expense	0	600	(1,032)	600	600	768	2,640	2,759	2,955	2,987	3,092	3,189	3,274	3,344	3,678	4,046	4,451	4,896	5,386
Other	2,978	(141)	0	0	0	(141)	0	0	0	0	0	0	0	0	0	0	0	0	0
Net Income (Loss) Non-GAAP	**(30,887)**	**(14,386)**	**(13,594)**	**(12,052)**	**(12,551)**	**(52,582)**	**30,325**	**13,577**	**(3,506)**	**42,645**	**128,112**	**100,855**	**149,465**	**177,555**	**219,693**	**254,618**	**283,974**	**306,052**	**327,850**
Diluted Earnings Per Share Non-GAAP	**($14.00)**	**($5.52)**	**($5.21)**	**($0.50)**	**($0.51)**	**($3.88)**	**$1.19**	**$0.51**	**($0.12)**	**$1.44**	**$4.12**	**$3.09**	**$4.36**	**$4.93**	**$5.81**	**$6.42**	**$6.82**	**$7.00**	**$7.14**
Basic Earnings Per Share Non-GAAP	($14.00)	($5.52)	($5.21)	($0.56)	($0.57)	($4.32)	$1.34	$0.57	($0.14)	$1.62	$4.64	$3.48	$4.92	$5.56	$6.55	$7.23	$7.68	$7.89	$8.05
Diluted Earnings Per Share GAAP	**($15.35)**	**($5.69)**	**($4.81)**	**($0.52)**	**($0.53)**	**($3.92)**	**$1.08**	**$0.40**	**($0.23)**	**$1.34**	**$4.02**	**$2.99**	**$4.27**	**$4.93**	**$5.81**	**$6.42**	**$6.82**	**$7.00**	**$7.14**
Basic Earnings Per Share GAAP	($15.35)	($5.69)	($4.81)	($0.59)	($0.60)	($4.38)	$1.22	$0.45	($0.26)	$1.51	$4.53	$3.37	$4.81	$5.56	$6.55	$7.23	$7.68	$7.89	$8.05
Diluted Shares Outstanding (th)	**2,207**	**2,607**	**2,609**	**24,186**	**24,828**	**13,558**	**25,573**	**26,851**	**28,194**	**29,603**	**31,084**	**32,638**	**34,270**	**35,983**	**37,782**	**39,671**	**41,655**	**43,738**	**45,925**
Basic Shares Outstanding (th)	2,207	2,607	2,609	21,389	22,031	12,159	22,692	23,826	25,018	26,269	27,582	28,961	30,409	31,930	33,526	35,203	36,963	38,811	40,751

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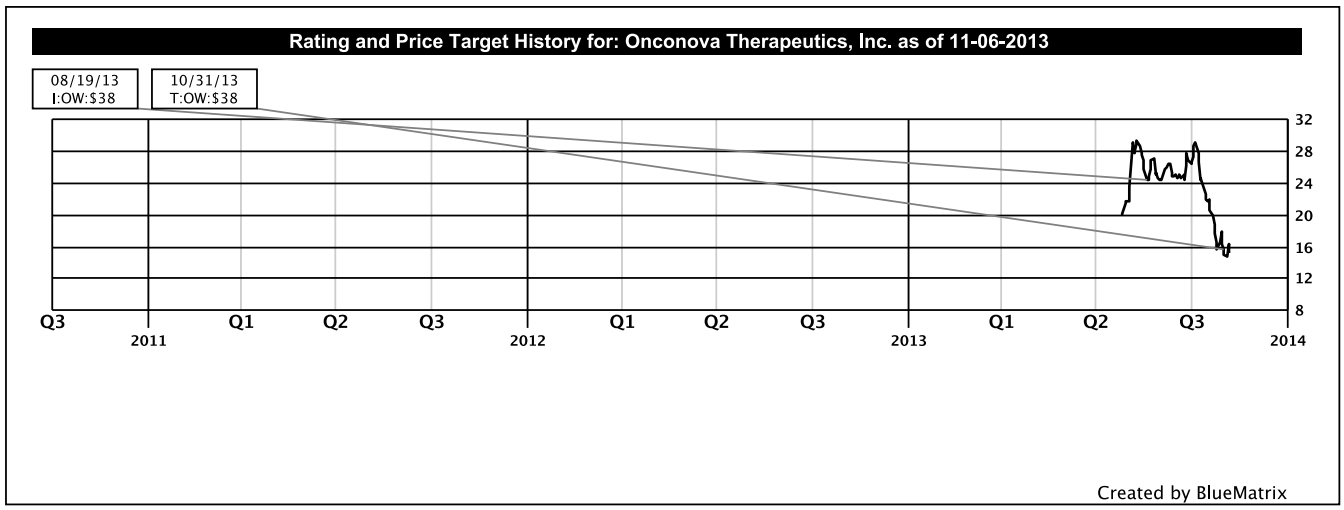

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N: Neutral
UW: Underweight
NA: Not Available
UR: Under Review

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Piper Jaffray

			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OW]	338	57.09	75	22.19
HOLD [N]	229	38.68	15	6.55
SELL [UW]	25	4.22	0	0.00

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Analyst Certification — Charles C. Duncan, PhD, Sr. Research Analyst
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