

Onconova Therapeutics, Inc. (ONTX)

Overweight

Near Term ASH Data Opens Door for 2014 Pipeline Progress

CONCLUSION

We are assuming coverage of Onconova at Overweight with a \$38 price target. We are encouraged by the preliminary Phase II data presented at ASCO for rigosertib in myelodysplasia (MDS) and look forward to a comprehensive update at ASH (abstracts released Nov. 7th). At ASCO'13 rigosertib showed a compelling interim response rate (50% transfusion independence) in low/intermediate-1 risk MDS patients in Phase II. In our view, investors shouldn't expect 50%+ RRs at ASH, though we think ~35% is a reasonable target for clinical benefit. We would see an effective answer to the urinary side effects and early biomarker data for determining responsive patients to be encouraging regarding this population and perhaps the ongoing Phase III trial in higher-risk patients. With multiple MDS-driven inflection points and potential upside in other hematological conditions and solid tumors (pancreatic cancer in Phase III), we reiterate our price target and Overweight rating on Onconova.

- **Expectations at ASH.** Onconova will present data from the completed Phase II in low/intermediate-1 risk MDS as well as data in high/intermediate-2 risk MDS. The data for high/intermediate-2 will not be interim data from the ongoing 2nd-line Phase III study, though that data may yet be presented before YE, but will be a synthesis/overview of prior data for rigosertib in this setting. While we expect the most watched data will be response rate (8-week transfusion independence) from the 1st-line low/intermediate-1 Phase II, we believe solutions to the urinary safety are also important and if the solution appears robust and easily implemented, this bodes well for future clinical developments, in our view.
- **Anticipated developments for rigosertib.** We believe the full Phase II data as presented at ASH will support discussions with the FDA regarding a Phase III design for low/intermediate-1 risk MDS. Onconova will likely seek a transfusion-independence endpoint similar to that used in the Phase II. Note that the FDA appears to have agreed with a non-overall survival endpoint for studies of Array's p38 inhibitor ARRY-614, based on the company's website.

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\$16.35

TARGET: US\$38.00

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

Charles C. Duncan, PhD

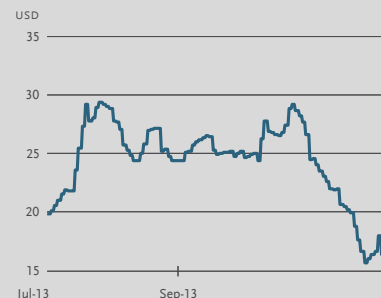
Sr. Research Analyst, Piper Jaffray & Co.
212 284-5025, charles.c.duncan@pjc.com

Roy Buchanan, Ph.D.

Research Analyst, Piper Jaffray & Co.
212 284-9458, roy.d.buchanan@pjc.com

Changes	Previous	Current
Rating	—	Overweight
Price Tgt	—	US\$38.00
FY13E Rev (mil)	US\$4.1	US\$3.7
FY14E Rev (mil)	—	US\$104.0
FY13E EPS	US\$(3.40)	US\$(3.92)
FY14E EPS	US\$1.18	US\$1.08
52-Week High / Low	US\$31.13 / US\$15.00	
Shares Out (mil)	20.8	
Market Cap. (mil)	US\$340.1	
Avg Daily Vol (ooo)	151	
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	7.4x	—	—	—	—	(15.35)	NM
2013E	1.1A	0.6A	1.0	1.0	3.7	91.9x	(5.69)A	(4.81)A	(0.52)	(0.53)	(3.92)	NM
2014E	—	—	—	—	104.0	3.3x	—	—	—	—	1.08	15.1x

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MDS is a competitive and evolving space. With relatively few treatment options for subsets of patients (mainly Vidaza/Dacogen in high risk, Revlimid in del5q low risk), but with a number of agents under investigation (summary from ASCO in Exhibit 1), MDS looks to be an exciting space for drug development in the coming months and years. Celgene has oral Vidaza and Revlimid (label extension) in Phase III studies and partner Acceleron has two agents in Phase II. Array is looking at inhibition of MAPK p38. While the space appears to be increasing in complexity and competition, we expect that many agents will eventually be used in combination and there are numerous investigations of combinations ongoing.

Rigosertib makes a compelling argument. Rigosertib has a non-overlapping set of targets (PI-3K alpha and beta, and indirectly polo-like kinase 1) and distinct mechanism of action vs. the other agents we are aware of in development for MDS, and given its good safety profile to date, we expect it to become part of the MDS treatment paradigm (both high risk and low risk). Initially this will be as a single agent based on the studies currently underway, which will allow the medical community to gain experience with the agent. Currently there are no cures for MDS outside stem cell transplant (SCT), so for patients ineligible for SCT, new and effective treatments are being sought.

Model updates. We have made modest updates to our model to reflect reported 2Q13 financials (see appended model). Our valuation is essentially unchanged outside a slight change in fully diluted shares projected for YE14 (Exhibit 2 for current valuation, Exhibit 3 for prior).

Exhibit 1

SUMMARY OF MDS AGENTS IN DEVELOPMENT

There are currently 348 interventional studies recruiting MDS patients (clinicaltrials.gov accessed 2/12/13)

• Lower Risk MDS	• Higher Risk MDS
– P38α MAPK inhibitors	– Tyrosine kinase inhibitors
– TGF-β inhibitors	• Rigosertib
– IDO inhibitors	• Erlotinib
– MDM2-P53 pathway modulation	– Aminopeptidase inhibitors
– TPO stimulants	– Hedgehog inhibitors
– Oral azacitidine	– Ruxolitinib for CMML
– Ezatiostat HCL	– PARP inhibitors
	– mTOR inhibitors
	– Clofarabine
	– Sapacitabine

Source: ASCO 2013

Exhibit 1

CURRENT ONCONOVA DCF VALUATION

<i>Assumed Discount Rate (%)</i>	10.0%
Discounted Net Cash Flow (2015-26)	\$842,058
<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	\$842,058
Add: Net Cash	129,698
Equity Value	\$971,756
Shares Outstanding 2014E (million)	25,573
Equity Value per Share	\$38.00

Source: Piper Jaffray

Exhibit 1

PRIOR ONCONOVA DCF VALUATION

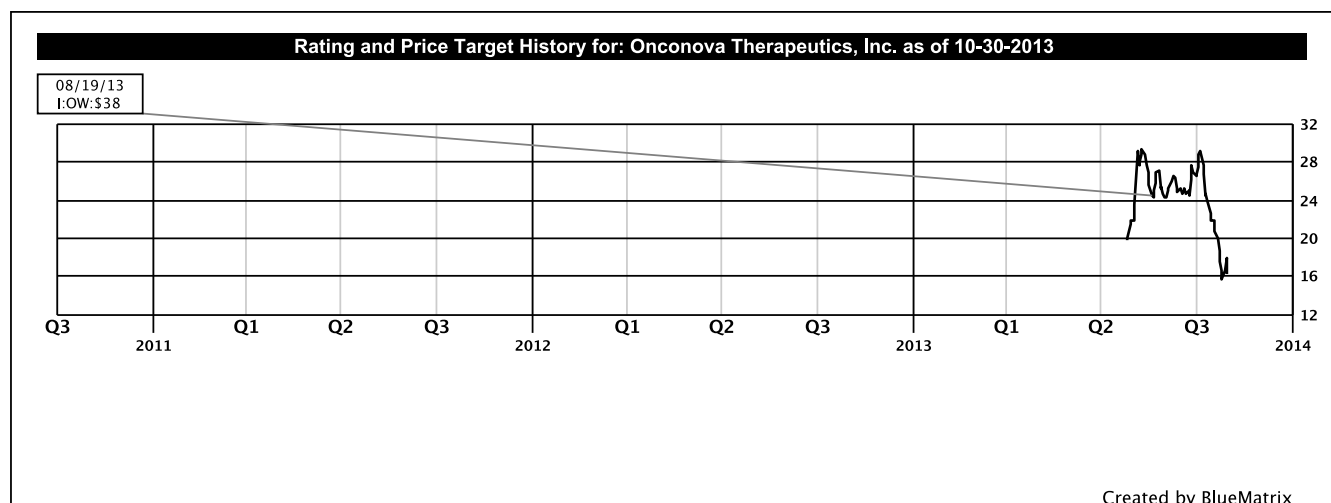
<i>Assumed Discount Rate (%)</i>	10.0%
Discounted Net Cash Flow (2015-26)	\$856,120
<i>Terminal Growth Rate (%)</i>	No TV
<i>Implied Terminal Year FCF Multiple</i>	0.0x
Present Value of Terminal Value	\$0
<i>Terminal Value as % of total</i>	0.0%
Enterprise Value	\$856,120
Add: Net Cash	117,853
Equity Value	\$973,973
Shares Outstanding 2014E (million)	25,602
Equity Value per Share	\$38

Source: Piper Jaffray

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
Int'l 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	788	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

Proprietary to Piper Jaffray & Co. October 31, 2013
ONTX: Charles Duncan; 212-284-5025
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			Count	Percent
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HOLD [N]	228	38.45	14	6.14
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Analyst Certification — Charles C. Duncan, PhD, Sr. Research Analyst — Roy Buchanan, Ph.D., Research Analyst

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