

Onconova Therapeutics (ONTX - \$1.91)

Results of Earlier Rigosertib 04-24 Study Reported at the ASCO Meeting Demonstrated Treatment Activities

ONTX presented a poster at the ASCO meeting, which highlighted the results from an earlier 04-24 study illustrating that rigosertib treatment afforded a positive correlative relationship of bone marrow blast (BMBL) response to overall survival.

- Details.** At the ASCO meeting, ONTX presented a poster highlighting positive clinical results from the Study 04-24. The results showed that median overall survival (OS) for patients who achieved marrow complete response (mCR) (n=14 or 22%) had not been reached as of the time of the analysis. Median OS of stable disease (SD) (n=30, or 47%), and progressive disease (PD) (n=15 or 23%) were 6.3 months and 3.3 months, respectively. If the Study 04-24 data combined with the prior Phase I/II (Study 04-21) results are considered, the OS for mCR, SD and PD were 11.8 months, 7.3 months and 3.9 months, respectively. The Study 04-24 enrolled 64 MDS patients who had 5-30% BMBL confirmed within 6 weeks pre-study and progression per International Working Group (IWG) 2006 criteria on or after HMAs within 2 years. The primary endpoint was relationship of best BMBL IWG response to OS by Kaplan Meier method and BMBL were used as a potential predictor for survival.
- Implications.** We believe the positive results from the Study 04-24 supports the notion that rigosertib is active as a potential 2nd-line MDS treatment. The outcome is also consistent with the earlier Phase I/II (Study 04-21) results, which later led to the advancement to the ONTIME Phase III study. Together, we continue to view the possible success of the ongoing INSPIRE study is the key binary value driver of ONTX share value. Near-term, the most critical event would be the anticipated interim analysis of the INSPIRE trial after the occurrence of 88 events (deaths), possibly in 2H17, for assessing the outcome on an intent-to-treat (ITT) basis. Also, if needed, a very high risk (based on IRSS-R VHR) patient basis analysis will be analyzed. This is to determine the subsequent clinical and regulatory path for the drug. We remain encouraged by the IV rigosertib development given it potentially has more than one clinical path moving forward. Also, several positive unrecognized prognostic factors were identified from the ONTIME trial to shape the design of the INSPIRE trial.
- Action.** We are reiterating our Buy rating and target price of \$10. Our valuation is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses. We believe ONTX shares remain undervalued given its two rigosertib formulations in late stage development as potential 1st- and 2nd-line MDS therapies.

Healthcare/Biotechnology

Ticker:	ONTX
Rating:	Buy
Price Target:	\$10.00

Trading Data:

Last Price (6/2/2017)	\$1.91
52-Week High (6/9/2016)	\$8.17
52-Week Low (5/31/2017)	\$1.78
Market Cap. (MM)	\$19
Shares Out. (MM)	4.427

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-1.23A	-0.74	-0.72	-0.73	-3.28	N.A.
FY-16A	-2.65	-1.96	-0.29	-0.80	-4.44	N.A.
FY-15A	-5.69	-4.13	-2.60	1.28	-10.54	N.A.
FY-14A	NA	NA	NA	NA	-29.41	N.A.

Yale Jen, Ph.D.

Managing Director/Senior
Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

Source: Laidlaw & Company estimates

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Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
Rigosertib	Myelodysplastic syndromes (MDS) - high risk	Potentially update Phase III study design for oral formulation azacitidine combination as first-line treatment	2Q/3Q17	***
		Potentially report Phase III (INSPIRE) interim results and make adjustment if needed	2H17	****
		Potentially complete Phase III (INSPIRE) patient recruitment	1Q18	***
		Potentially report Phase III (INSPIRE) top-line results	2H18	*****
		Potentially start oral formulation azacitidine combination Phase III study as first-line treatment	2018	***
	Acute myeloid leukemia (AML)	Presentation Phase I/II trial data at MDS Foundation and Congress of EHA meetings	2Q17	***

*** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative

Source: Laidlaw & Company and company presentation

Major Risks

Clinical study failure could have a major impact on ONTX share value. Given the study design of the ongoing rigosertib INSPIRE Phase III study was based on outcomes from retrospective analysis of a prior failed Phase III clinical study (ONTIME), there are certain inherited risks beyond that of a typical Phase III study as post hoc analysis could potentially identify any favorable features based on the set criteria for analysis. Also, given rigosertib is the only clinically advanced asset in ONTX's portfolio, negative results of the Phase III and additional clinical studies could have a materially negative impact on the shareholder value.

Without a Ras-targeted drug being clinically successful and approved, this molecular target has not gained sufficient clinical validation and therefore has greater uncertainty. Although the relationship between Ras mutations and tumorigenesis was known for a few decades, there are no drugs that target Ras that have been approved. Given Ras has been characterized as potentially "undruggable", there are potentially greater clinical risks for a Ras targeting therapy compared to drugs that target other more proven molecular targets or development platforms.

Product may not be approved or reach anticipated sales. Although ONTX's current pipeline products, especially the leading rigosertib, have exhibited the potential to generate positive clinical outcomes from current and future trials; it remains too early to project whether any of these products would be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and the possible changes in pricing flexibility and payer reimbursement. A revenue outlook below expectations could also negatively affect ONTX shareholder value.

Additional financings could dilute shareholder value. Although the company had ~\$25MM cash pro forma at April 2017, ONTX most likely would need more financial resources going forward if they want to complete the rigosertib clinical developments and potentially expand and further develop their additional pipeline. Should the future operational expenses, especially from R&D and COGs, increase significantly, products not receive FDA approval, or product revenue not reach expectations; the company might need to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

Figure 1: Income Statement

Onconova Therapeutics - Income Statement													
(\$'000)	2015	2016	1Q17	2Q17E	3Q17E	4Q17E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenue													
Rigosertib sale									16,200	50,708	122,096	218,574	313,595
Non-product revenue	11,456	5,546	210	180	175	190	755	778	2,050	2,100	1,000	500	0
Total revenues	11,456	5,546	210	180	175	190	755	778	18,250	52,808	123,096	219,074	313,595
COGS									1,620	5,071	12,210	21,857	31,360
Net revenue									14,580	45,637	109,886	196,717	282,236
Total net revenue								778	16,630	47,737	110,886	197,217	282,236
General and administrative	9,533	9,178	2,116	2,158	2,223	2,268	8,765	9,729	10,605	11,453	12,140	12,626	13,005
Research and development	25,895	20,071	4,886	4,984	5,133	5,287	20,290	23,740	26,588	29,513	31,579	28,421	28,989
Marketing and sales									22,000	23,540	24,717	26,447	27,770
Total operating costs and expenses	35,428	29,249	7,002	7,142	7,356	7,555	29,055	33,469	59,193	64,506	68,436	67,494	69,764
Operating Incomes (losses)	(23,972)	(23,703)	(6,792)	(6,962)	(7,181)	(7,365)	(28,300)	(32,691)	(42,563)	(16,769)	42,450	129,723	212,472
Change in fair value of warrant liability		3,988	(1,549)	(300)	100	140	(1,609)	(400)	(450)	(400)	(350)	(350)	(350)
Interest expense							0						
Other income, net	(35)	62		10	10	10	30	33	36	40	44	48	53
Net loss before income taxes	(24,007)	(19,653)	(8,341)	(7,252)	(7,071)	(7,215)	(29,879)	(33,058)	(42,977)	(17,129)	42,144	129,421	212,175
Income taxes	16	14							0	0	15,593	47,886	78,505
Net Income (Loss)	(24,023)	(19,667)	(8,341)	(7,252)	(7,071)	(7,215)	(29,879)	(33,058)	(42,977)	(17,129)	26,551	81,535	133,670
Net loss attributable to non-controlling interest	44												
Net loss attributable to Onconova Therapeutics, Inc	(23,979)	(19,667)	(8,341)	(7,252)	(7,071)	(7,215)	(29,879)	(33,058)	(42,977)	(17,129)	26,551	81,535	133,670
Accretion of redeemable convertible preferred stock													
Net loss applicable to common stockholders	(23,979)	(19,667)	(8,341)	(7,252)	(7,071)	(7,215)	(29,879)	(33,058)	(42,977)	(17,129)	26,551	81,535	133,670
Basic and diluted net loss per share	(\$10.54)	(\$4.44)	(\$1.23)	(\$0.74)	(\$0.72)	(\$0.73)	(\$3.28)	(\$2.73)	(\$2.85)	(\$0.95)	\$1.32	\$3.86	\$6.30
Shares used to calculate the basic and diluted net loss per share	2,274	4,427	6,771	9,851	9,881	9,901	9,101	12,101	15,101	18,101	20,101	21,101	21,201
Margin Analysis (% of Sales/Revenue)													
Costs of goods									10%	10%	10%	10%	10%
R&D	83%	165%	1008%	1199%	1270%	1193%	1161%	1251%	58%	22%	10%	6%	4%
SG&A	226%	362%	2327%	2769%	2933%	2783%	2687%	3053%	146%	56%	26%	13%	9%
Operating Income (loss)	-209%	-427%	-3234%	-3868%	-4104%	-3876%	-3748%	-4204%	-233%	-32%	34%	59%	68%
Net Income	-210%	-355%	-3972%	-4029%	-4041%	-3797%	-3957%	-4251%	-235%	-32%	22%	37%	43%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	1332%	-52%	-86%	-92%	-89%	10%	-86%	3%	2247%	189%	133%	78%	43%
G&A	-37%	-4%	-33%	4%	13%	16%	-5%	11%	9%	8%	6%	4%	3%
R&D	-48%	-22%	-16%	-10%	29%	13%	1%	17%	12%	11%	7%	-10%	2%
M&S										7%	5%	7%	5%
Operating Income (Losses)	-62%	-17%	-22%	-7%	23%	14%	-1%	15%	77%	9%	6%	-1%	3%
Pretax Income	-62%	-18%	15%	35%	342%	33%	52%	11%	30%	-60%	-346%	207%	64%
Net Income	-62%	-18%	15%	35%	342%	32%	52%	11%	30%	-60%	-255%	207%	64%
EPS	-64%	-58%	-54%	-63%	143%	-9%	-26%	-17%	4%	-67%	-240%	193%	63%
Yale Jen, Ph.D. 212-953-4978													

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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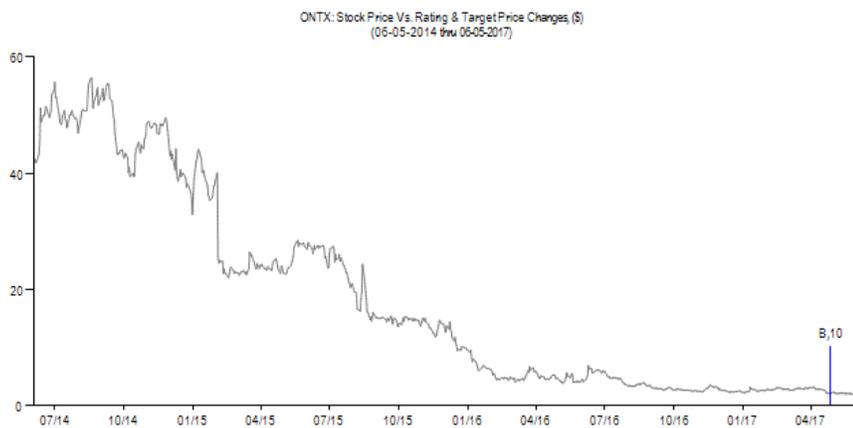
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3 Year Rating Change History

Date	Rating	Closing Price (\$)
04/27/2...	Buy (B)	2.13

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
04/27/2...	10.00	2.13

Source: Laidlaw & Company

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
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Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.22%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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