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EQUITY RESEARCH
Company Report

January 17, 2018

Onconova Therapeutics (ONTX - $1.74)

Healthcare/Biotechnology

INSPIRE Trial Continues - Adding More Patients and Likely Greater Confidence of Success

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

ONTX announced this morning that after their interim analysis, the rigosertib in 2nd-line MDS Phase III (INSPIRE) trial will continue with the addition of 135 more patients (a total of 360) for potential final data readout covering either high risk [on an intent to treat (ITT) basis] or very high risk (VHR) MDS patients.

- **Details.** After the interim analysis (after 80 deaths), ONTX will continue the INSPIRE trial along the ITT study population pathway and add 135 more patients to the original target of 225 patients, based on the DMC's recommendations. Management indicated that 170 patients have been recruited so far with 70% of them characterized as VHR. During the conference call, ONTX indicated that the overall study design has not been changed except for adding more patients. As such, no IRB amendment or FDA approval will be required. The statistical analysis remains the same, with p value of 0.04 and 0.01, respectively for achieving statistical significance in the ITT and VHR MDS population, respectively. The powering assumption has changed to 90% from 80%. For the final analysis, ONTX will review the outcome from ITT first, and if it is not robust, they will then examine the outcome of the VHR cohort. As such, the two shots on goal objective remains intact. ONTX indicated that current plan for the completion of patient enrollment is by year-end 2018, which is six additional more months than the initial goal based on the total patients of 225. As such, we estimate the topline data could be available in 2H19 with filing in late 2019 or 2020. The primary endpoint is OS and it will be assessed when 288 deaths occur (80% of the 360 patients). ONTX also indicated that patient recruitment rate latterly was on average at mid-teen per month.
- **Implications.** We view today's news overall positive given the interim look and the subsequent adjustments could likely increase the odd of success for the INSPIRE trial even if additional patients are needed for the study. It is also important that the two options (ITT and VHR) for potentially positive outcome and approval remains intact. In addition, even there are more patients needed for the study, the additional time required for the completion of the trial and topline data readout still is relatively modest (two to three quarters), in our estimate.
- **Action.** We reiterate our Buy rating and $10 target price. Our valuation is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses. We believe ONTX remains undervalued given its two rigosertib formulations in late stage development as potential 1st- and 2nd-line MDS therapies.

Trading Data:

Last Price (1/16/2018)	$1.74
52–Week High (4/4/2017)	$3.88
52–Week Low (12/13/2017)	$1.36
Market Cap. (MM)	$17
Shares Out. (MM)	10.77

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-1.23A	-0.29A	-0.71A	-0.61	-2.69	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.

Source: Laidlaw & Company estimates

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Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
Rigosertib	Myelodysplastic syndromes (MDS) - high risk	Potentially report Phase III (INSPIRE) interim results and make adjustment if needed	**Early 1Q18**	****
		Potentially complete Phase III (INSPIRE) patient recuritment	**1H19**	***
		Potentially report Phase III (INSPIRE) top-line results	**2020**	*****
		Potentially finalize Phase III study design for oral formulation azacitidine combination as first-line treatment and with possiblbe SPA designation	**2018**	***
		Potentially start oral formulation azacitidine combination Phase III study as first-line treatment	**2018**	***
	Pediatric RASopathies	Potentially start Phase I study	**2018**	***
		Additional business developments	**2018**	****

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

Source: Laidlaw & Company and company presentation

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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 ~$8MM cash by the end of 3Q17, 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.

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Figure 1: Income Statement

Onconova Therapeutics - Income Statement

($'000)	2015	2016	1Q17	2Q17	3Q17	4Q17E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenue													
Rigosertib sale										16,200	50,708	122,096	218,574
Non-product revenue	11,456	5,546	210	324	110	190	834	523	2,050	2,100	1,000	500	0
Total revenues	11,456	5,546	210	324	110	190	834	523	2,050	18,300	51,708	122,596	218,574
COGS									0	1,620	5,071	12,210	21,857
Net revenue									0	14,580	45,637	109,886	196,717
Total net revenue								523	2,050	16,680	46,637	110,386	196,717
General and administrative	9,533	9,178	2,116	1,779	1,728	1,693	7,316	7,551	8,230	8,889	9,422	9,799	10,093
Research and development	25,895	20,071	4,886	4,614	5,141	5,192	19,833	20,143	22,560	25,041	26,794	24,115	24,597
Marketing and sales									22,000	23,540	24,717	26,447	27,770
Total operating costs and expenses	35,428	29,249	7,002	6,393	6,869	6,886	27,150	27,694	52,790	57,470	60,934	60,361	62,460
Operating Incomes (losses)	(23,972)	(23,703)	(6,792)	(6,069)	(6,759)	(6,696)	(26,316)	(27,171)	(50,740)	(40,791)	(14,296)	50,025	134,257
Change in fair value of warrant liability		3,988	(1,549)	3,474	(210)	140	1,855	(2,468)	(450)	(400)	(350)	(350)	(350)
Interest expense							0						
Other income, net	(35)	62	0	11	8	10	29	45	50	54	60	66	72
Net loss before income taxes	(24,007)	(19,653)	(8,341)	(2,584)	(6,961)	(6,546)	(24,432)	(29,594)	(51,141)	(41,136)	(14,587)	49,741	133,979
Income taxes	16	14							0	0	0	18,404	49,572
Net Income (Loss)	(24,023)	(19,667)	(8,341)	(2,584)	(6,961)	(6,546)	(24,432)	(29,594)	(51,141)	(41,136)	(14,587)	31,337	84,407
Net loss attributable to non-controlling interest	44												
Net loss attributable to Onconova Therapeutics, Inc	(23,979)	(19,667)	(8,341)	(2,584)	(6,961)	(6,546)	(24,432)	(29,594)	(51,141)	(41,136)	(14,587)	31,337	84,407
Accretion of redeemable convertible preferred stock													
Net loss applicable to common stockholders	(23,979)	(19,667)	(8,341)	(2,584)	(6,961)	(6,546)	(24,432)	(29,594)	(51,141)	(41,136)	(14,587)	31,337	84,407
Basic and diluted net loss per share	($10.54)	($4.44)	($1.23)	($0.29)	($0.71)	($0.61)	($2.69)	($2.03)	($2.91)	($2.00)	($0.65)	$1.33	$3.57
Shares of the basic and diluted net loss	2,274	4,427	6,771	8,999	9,851	10,771	9,098	14,571	17,571	20,571	22,571	23,571	23,671
Margin Analysis (% of Sales/Revenue)													
Costs of goods									10%	10%	10%	10%	10%
R&D	83%	165%	1008%	549%	1571%	891%	877%	1444%	401%	49%	18%	8%	5%
SG&A	226%	362%	2327%	1424%	4674%	2733%	2378%	3851%	1100%	137%	52%	20%	11%
Operating Income (loss)	-209%	-427%	-3234%	-1873%	-6145%	-3524%	-3155%	-5195%	-2475%	-223%	-28%	41%	61%
Net Income	-210%	-355%	-3972%	-798%	-6328%	-3445%	-2929%	-5658%	-2495%	-225%	-28%	26%	39%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	1332%	-52%	-86%	-86%	-93%	10%	-85%	-37%	292%	793%	183%	137%	78%
G&A	-37%	-4%	-33%	-15%	-13%	-13%	-20%	3%	9%	8%	6%	4%	3%
R&D	-48%	-22%	-16%	-17%	29%	11%	-1%	2%	12%	11%	7%	-10%	2%
M&S										7%	5%	7%	5%
Operating Income (Losses)	-62%	-17%	-22%	-16%	15%	4%	-7%	2%	91%	9%	6%	-1%	3%
Pretax Income	-62%	-18%	15%	-52%	335%	20%	24%	21%	73%	-20%	-65%	-441%	169%
Net Income	-62%	-18%	15%	-52%	335%	20%	24%	21%	73%	-20%	-65%	-315%	169%
EPS	-64%	-58%	-54%	-85%	140%	-24%	-40%	-24%	43%	-31%	-68%	-306%	168%

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

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Additional information available upon request.

‡ Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

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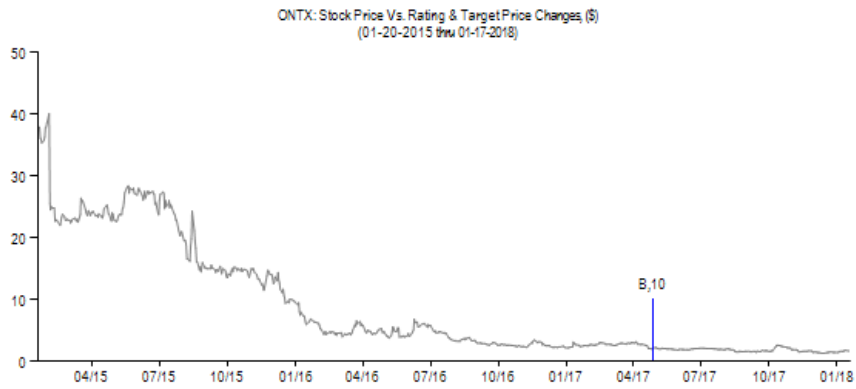
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
04/27/2017	Buy (B)	2.13

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
04/27/2017	10.00	2.13

Source: Laidlaw & Company **Created by: Blue-Compass.net**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	66.67%	29.41%	1.96%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	1.96%	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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