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EQUITY RESEARCH
Company Report

January 4, 2018

Onconova Therapeutics (ONTX - $1.58)

Healthcare/Biotechnology

Several Rigosertib Developments Underway

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

ONTX reported this morning the R&D progress with the National Cancer Institute (NCI) for rigosertib in pediatric RASopathies. Further, our discussions with the management afforded additional details on multiple program developments.

- **Details.** ONTX has formed a Cooperative Research and Development Agreement (CRADA) with the NCI to develop rigosertib in pediatric cancer associated RASopathies. NCI will conduct both preclinical laboratory studies and a clinical trial, which potentially could start in 2018. ONTX is responsible for supplying rigosertib and providing initial funding towards non-clinical studies. In addition, ONTX will focus on the development of Juvenile Myelomonocytic Leukemia (JMML), another incurable pediatric RASopathy for which the only treatment is allogenic hematopoietic stem cell transplant. Our discussions with management indicated that the initial RASopathies preclinical work already started in mid-2017 by the NCI. The RASopathies are rare diseases with hereditary mutations causing defects in the Ras effector pathways. Given their etiological cause, RASopathies is one group of difficult-to-treat diseases where restoring Ras could potentially create major clinical benefits. Further, our discussions with management also indicated that the triggering event (88 deaths) for starting the interim analysis for the INSPIRE study has been reached and the analysis outcome would potentially be available in early 1Q18 (we estimate later in January), as the company has guided before. ONTX also indicated that besides the recent ON 123300 (CDK4/6 and ARK5 dual inhibitor) clinical collaboration with the Chinese-based HanX Biopharmaceuticals, additional business developments and collaboration opportunities for this compound and rigosertib exist going forward in 2018 and beyond.
- **Implications.** We view today's news provide ONTX additional shots on goal for rigosertib in addition to the upcoming interim data readout of INSPIRE study. We believe three potential different scenarios for interim data readouts (except futility) for future development: ITT, very high risk, very high risk with more patients, could represent different outlooks for rigosertib as potential 2nd-line MDS therapy. In addition, we view potential more clinical data (~40 patients) to be available later in 2018 regarding rigosertib plus azacitidine as a potential 1st-line MDS therapy could be additional driver for ONTX share value.
- **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 (1/3/2018)	$1.51
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	-0.66	-2.75	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	**1H18**	***
		Potentially report Phase III (INSPIRE) top-line results	**2H18**	*****
		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	313,595
Non-product revenue	11,456	5,546	210	324	110	190	834	859	2,050	2,100	1,000	500	0
Total revenues	11,456	5,546	210	324	110	190	834	859	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								859	16,630	47,737	110,886	197,217	282,236
General and administrative	9,533	9,178	2,116	1,779	1,728	1,693	7,316	8,121	8,852	9,560	10,134	10,539	10,855
Research and development	25,895	20,071	4,886	4,614	5,141	5,192	19,833	23,205	25,990	28,849	30,868	27,781	28,337
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	31,326	56,842	61,949	65,719	64,768	66,962
Operating Incomes (losses)	(23,972)	(23,703)	(6,792)	(6,069)	(6,759)	(6,696)	(26,316)	(30,467)	(40,212)	(14,212)	45,167	132,449	215,274
Change in fair value of warrant liability		3,988	(1,549)	3,474	(210)	140	1,855	(400)	(450)	(400)	(350)	(350)	(350)
Interest expense							0						
Other income, net	(35)	62		11	8	10	29	32	35	39	42	47	51
Net loss before income taxes	(24,007)	(19,653)	(8,341)	(2,584)	(6,961)	(6,546)	(24,432)	(30,835)	(40,627)	(14,573)	44,860	132,146	214,975
Income taxes	16	14							0	0	16,598	48,894	79,541
Net Income (Loss)	(24,023)	(19,667)	(8,341)	(2,584)	(6,961)	(6,546)	(24,432)	(30,835)	(40,627)	(14,573)	28,262	83,252	135,434
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)	(30,835)	(40,627)	(14,573)	28,262	83,252	135,434
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)	(30,835)	(40,627)	(14,573)	28,262	83,252	135,434
Basic and diluted net loss per share	($10.54)	($4.44)	($1.23)	($0.29)	($0.71)	($0.66)	($2.75)	($2.59)	($2.73)	($0.81)	$1.42	$3.98	$6.45
Shares used to calculate the basic and diluted net loss per share	2,274	4,427	6,771	8,999	9,851	9,951	8,893	11,893	14,893	17,893	19,893	20,893	20,993
Margin Analysis (% of Sales/Revenue)													
Costs of goods									10%	10%	10%	10%	10%
R&D	83%	165%	1008%	549%	1571%	891%	877%	945%	49%	18%	8%	5%	3%
SG&A	226%	362%	2327%	1424%	4674%	2733%	2378%	2701%	142%	55%	25%	13%	9%
Operating Income (loss)	-209%	-427%	-3234%	-1873%	-6145%	-3524%	-3155%	-3547%	-220%	-27%	37%	60%	69%
Net Income	-210%	-355%	-3972%	-798%	-6328%	-3445%	-2929%	-3590%	-223%	-28%	23%	38%	43%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	1332%	-52%	-86%	-86%	-93%	10%	-85%	3%	2024%	189%	133%	78%	43%
G&A	-37%	-4%	-33%	-15%	-13%	-13%	-20%	11%	9%	8%	6%	4%	3%
R&D	-48%	-22%	-16%	-17%	29%	11%	-1%	17%	12%	11%	7%	-10%	2%
M&S										7%	5%	7%	5%
Operating Income (Losses)	-62%	-17%	-22%	-16%	15%	4%	-7%	15%	81%	9%	6%	-1%	3%
Pretax Income	-62%	-18%	15%	-52%	335%	20%	24%	26%	32%	-64%	-408%	195%	63%
Net Income	-62%	-18%	15%	-52%	335%	20%	24%	26%	32%	-64%	-294%	195%	63%
EPS	-64%	-58%	-54%	-85%	140%	-18%	-38%	-6%	5%	-70%	-274%	180%	62%

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

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RATINGS INFORMATION

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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