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EQUITY RESEARCH
Company Report

August 15, 2017

Onconova Therapeutics (ONTX - $1.91)

Healthcare/Biotechnology

2Q17: Focus Remains on the INSPIRE Study Interim Data Readout in 4Q17

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

ONTX reported 2Q17 financial results this morning with a net loss of ($2.6MM) vs. Laidlaw ($7.2MM) and the Street ($6.6MM) estimates. The main discrepancy, we believe, is a ~$3.5MM non-cash loss of change in fair value of warrant liability. Net loss/share was ($0.29) vs. ($0.74) for Laidlaw and ($0.71) of the Street. ONTX ended 2Q17 with ~$15MM cash and plus the recent financing, we believe ONTX should have sufficient support for operations into 2018.

- **INSPIRE trial updates.** ONTX indicated that patient recruitment of the study slowed down in the summer. Management, however, remained confident that the interim analysis (after 88 events or deaths) should occur in 4Q17, which is overall in-line with the prior guidance of 2H17. Further, ONTX is finalizing the statistical analysis plan (SAP) for the interim and top-line analysis. The company needs to resolve various differences of statistical analyses among different regulatory agencies (FDA, EMA and Japanese regulatory agency). As such, ONTX expects to establish the final SAP by late 3Q17 or 4Q17. Given the recent seasonality-related patient recruitment slow down, management is uncertain whether patient enrollment for the full study could be completed in 1Q18 as guided before; and provided a more conservative projection. We estimate that completion of patient enrollment remains likely in 1H18 barring any unforeseeable developments, and with topline results potentially in late 1H18 or early 2H18.
- **Oral rigosertib/azacitidine combination for 1st-line MDS updates.** ONTX currently is conducting a Phase I/II expansion phase study with up to 40 patients. Management is in the process of designing the Phase III trial with the potential for an SPA designation by the FDA. The objective of the expansion study is to optimize dosing and schedule of administration. The potential outcome could potentially provide more data points (both safety and efficacy) that could further facilitate a better design of the Phase III trial, while also leveraging the clinical sites that already are familiar with the dosing the oral rigosertib/azacitidine combination regimen. We estimate the final Phase III design and the request for SPA designation could potentially occur in 2018.
- **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.

Trading Data:

Last Price (8/14/2017)	$1.91
52–Week High (8/18/2016)	$4.12
52–Week Low (5/31/2017)	$1.78
Market Cap. (MM)	$18
Shares Out. (MM)	4.427

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-1.23A	-0.29A	-0.70	-0.71	-2.79	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 2017 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	**4Q17**	****
		Potentially complete Phase III (INSPIRE) patient recuritment	**1H18**	***
		Potentially report Phase III (INSPIRE) top-line results	**2018**	*****
		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**	***

***** / ***** 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 ~$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.

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Figure 1: Income Statement

Onconova Therapeutics - Income Statement

($'000)	2015	2016	1Q17	2Q17	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	324	175	190	899	926	2,050	2,100	1,000	500	0
Total revenues	11,456	5,546	210	324	175	190	899	926	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								926	16,630	47,737	110,886	197,217	282,236
General and administrative	9,533	9,178	2,116	1,779	1,832	1,869	7,596	8,432	9,191	9,926	10,522	10,943	11,271
Research and development	25,895	20,071	4,886	4,614	4,752	4,895	19,147	22,402	25,091	27,851	29,800	26,820	27,357
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	6,585	6,764	26,744	30,834	56,282	61,317	65,039	64,210	66,397
Operating Incomes (losses)	(23,972)	(23,703)	(6,792)	(6,069)	(6,410)	(6,574)	(25,845)	(29,908)	(39,652)	(13,580)	45,847	133,007	215,839
Change in fair value of warrant liability		3,988	(1,549)	3,474	100	140	2,165	(400)	(450)	(400)	(350)	(350)	(350)
Interest expense							0						
Other income, net	(35)	62		11	10	10	31	34	38	41	45	50	55
Net loss before income taxes	(24,007)	(19,653)	(8,341)	(2,584)	(6,300)	(6,424)	(23,649)	(30,274)	(40,064)	(13,939)	45,542	132,707	215,543
Income taxes	16	14							0	0	16,851	49,101	79,751
Net Income (Loss)	(24,023)	(19,667)	(8,341)	(2,584)	(6,300)	(6,424)	(23,649)	(30,274)	(40,064)	(13,939)	28,692	83,605	135,792
Net loss attributable to non-controlling interest	44												
Net loss attributable to Onconova Therapeutics, Inc	(23,979)	(19,667)	(8,341)	(2,584)	(6,300)	(6,424)	(23,649)	(30,274)	(40,064)	(13,939)	28,692	83,605	135,792
Accretion of redeemable convertible preferred stock													
Net loss applicable to common stockholders	(23,979)	(19,667)	(8,341)	(2,584)	(6,300)	(6,424)	(23,649)	(30,274)	(40,064)	(13,939)	28,692	83,605	135,792
Basic and diluted net loss per share	($10.54)	($4.44)	($1.23)	($0.29)	($0.70)	($0.71)	($2.79)	($2.64)	($2.77)	($0.80)	$1.47	$4.09	$6.60
Shares used to calculate the basic and diluted net loss per share	2,274	4,427	6,771	8,999	9,029	9,049	8,462	11,462	14,462	17,462	19,462	20,462	20,562
Margin Analysis (% of Sales/Revenue)													
Costs of goods									10%	10%	10%	10%	10%
R&D	83%	165%	1008%	549%	1047%	984%	845%	911%	50%	19%	9%	5%	4%
SG&A	226%	362%	2327%	1424%	2716%	2576%	2130%	2419%	137%	53%	24%	12%	9%
Operating Income (loss)	-209%	-427%	-3234%	-1873%	-3663%	-3460%	-2875%	-3230%	-217%	-26%	37%	61%	69%
Net Income	-210%	-355%	-3972%	-798%	-3600%	-3381%	-2631%	-3269%	-220%	-26%	23%	38%	43%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	1332%	-52%	-86%	-86%	-89%	10%	-84%	3%	1871%	189%	133%	78%	43%
G&A	-37%	-4%	-33%	-15%	-7%	-4%	-17%	11%	9%	8%	6%	4%	3%
R&D	-48%	-22%	-16%	-17%	19%	4%	-5%	17%	12%	11%	7%	-10%	2%
M&S										7%	5%	7%	5%
Operating Income (Losses)	-62%	-17%	-22%	-16%	10%	2%	-9%	15%	83%	9%	6%	-1%	3%
Pretax Income	-62%	-18%	15%	-52%	294%	18%	20%	28%	32%	-65%	-427%	191%	62%
Net Income	-62%	-18%	15%	-52%	294%	18%	20%	28%	32%	-65%	-306%	191%	62%
EPS	-64%	-58%	-54%	-85%	137%	-11%	-37%	-5%	5%	-71%	-285%	177%	62%

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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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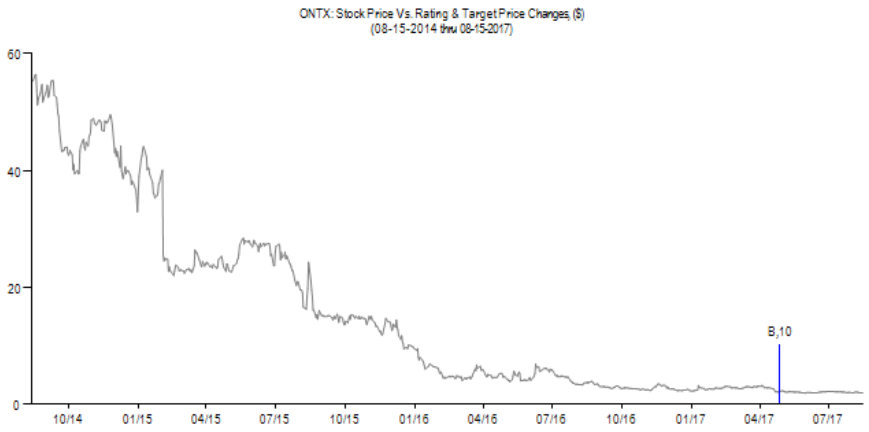
Rating and Price Target Change History



3 Year Rating Change History

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

3 Year Price Change History

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

Source: Laidlaw & Company **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.	63.04%	30.43%	2.17%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.35%	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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