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EQUITY RESEARCH
Company Report

August 15, 2018

Onconova Therapeutics (ONTX - $0.45)

Healthcare/Biotechnology

2Q18: Overall an Uneventful Quarter with INSPIRE Phase III Study Readout Potentially in Late 2019 or Early 2020

Ticker:	**ONTX**
Rating:	**Buy**
Price Target:	**$2.80**

ONTX reported 2Q18 financial results yesterday with a net loss of ($5.1MM) vs. Laidlaw ($7.6MM) and the Street ($6.2MM) estimates. Net loss/share was ($0.34) vs. ($0.62) for Laidlaw and ($0.24) of the Street. ONTX ended 2Q18 with cash of $29.5MM, sufficient for supporting operations into 2H19, in our opinion.

- **INSPIRE study update.** The rigosertib in r/r higher-risk (HR) MDS Phase III (INSPIRE) study is ongoing and will enroll 360 patients with topline results available once 288 death events (80% of 360) occur. ONTX anticipates the patient recruitment could potentially complete in 2H19. The primary endpoint is OS with objective of 37% improvements. The study has the option for analyzing outcomes from the ITT first, and if it is not robust enough, then the VHR cohort. Given the OS of the control group is relatively short (~ 4 moths), it is possible that topline readout could occur relatively close to (or even before) the completion of patient enrollment. As such, the topline readout could slate to late 2019 or early 2020 if the pace of patient recruitment is as projected. Based on this timeline, estimated NDA filing could occur in 2020 with possible approval in late 2020 or 2021.
- **Oral rigosertib/azacitidine combo as 1st-line HR-MDS development updates.** With the completion of expanded patient enrollment (45 addition) of the Phase II expansion trial, we believe ONTX could report more matured results in 4Q18, likely at the ASH conference. ONTX expects to start the Phase III trial if additional dilutive or non-dilutive financial resources are available.
- **ON 123300 development updates.** Chinese partner HanX Biopharmaceuticals is conducting preclinical studies for a potential clinical study in China. The preparatory work could also facilitate the potential clinical studies in the U.S, which ONTX will start possibly in 2019, pending funding. Examples of possible indications that might benefit from ON 123300 (inhibitor of CDK4/6 and ARK5) include CDK4/6 refractory/relapsed metastatic breast cancer, multiple myeloma and colorectal cancer.
- **Action.** We reiterate our Buy rating and 12-month target price of $2.80. 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 (8/14/20188)	$0.45
52–Week High (10/12/2017)	$2.83
52–Week Low (5/15/2018)	$0.33
Market Cap. (MM)	$31.7
Shares Out. (MM)	77.6

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	-0.34A	-0.07A	-0.09	-0.08	-0.42	N.A.
FY-17A	-1.23	-0.29	-0.71	-0.60	-2.68	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.

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 complete Phase III (INSPIRE) patient recuritment	**2H19**	***
		Potentially report Phase III (INSPIRE) top-line results	**Late 2H19/1H20**	*****
		Potentially finalize Phase III study design for oral formulation azacitidine combination as first-line treatment and with possiblbe SPA designation	**2H18**	***
		Potentially start oral formulation azacitidine combination Phase III study as first-line treatment	**2019**	***
	Pediatric RASopathies	Potentially report Phase I study results	**2019/2020**	***
ON 123300	Solid tumors	Potentially start Phase I study pending on funding	**2019**	***
		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 ~$29MM cash, 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	2017	1Q18	2Q18	3Q18E	4Q18E	2018E	2019E	2020E	2021E	2022E	2023E
Revenue													
Rigosertib sale										16,200	50,708	122,096	218,574
Non-product revenue	11,456	5,546	787	564	485	134	139	1,322	1,150	2,100	1,000	500	0
Total revenues	11,456	5,546	787	564	485	134	139	1,322	1,150	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				564	485	134	139	1,322	1,150	16,680	46,637	110,386	196,717
General and administrative	9,533	9,178	7,405	1,889	2,054	2,075	2,095	8,113	8,843	9,550	10,123	10,528	10,844
Research and development	25,895	20,071	19,119	4,577	4,070	3,744	3,557	15,949	17,862	19,827	21,215	19,094	19,476
Marketing and sales										22,000	23,100	24,717	25,953
Total operating costs and expenses	35,428	29,249	26,524	6,466	6,124	5,819	5,652	24,061	26,705	51,378	54,439	54,339	56,273
Operating Incomes (losses)	(23,972)	(23,703)	(25,737)	(5,902)	(5,639)	(5,685)	(5,513)	(22,739)	(25,555)	(34,698)	(7,802)	56,047	140,444
Change in fair value of warrant liability		3,988	1,628	812	513	(145)	390	1,570	(450)	(400)	(350)	(350)	(350)
Gain on dissolution of GBO					693								
Interest expense			0										
Other income, net	(35)	62	30	0	112	12	12	136	150	165	181	199	219
Net loss before income taxes	(24,007)	(19,653)	(24,079)	(5,090)	(4,321)	(5,818)	(5,111)	(21,033)	(25,856)	(34,933)	(7,970)	55,896	140,313
Income taxes	16	14	13						0	0	0	20,682	51,916
Net Income (Loss)	(24,023)	(19,667)	(24,092)	(5,090)	(4,321)	(5,818)	(5,111)	(21,033)	(25,856)	(34,933)	(7,970)	35,215	88,397
Net loss attributable to non-controlling interest	44				(163)								
Net loss attributable to Onconova Therapeutics, Inc	(23,979)	(19,667)	(24,092)	(5,090)	(4,484)	(5,818)	(5,111)	(21,033)	(25,856)	(34,933)	(7,970)	35,215	88,397
Accretion of redeemable convertible preferred stock													
Net loss applicable to common stockholders	(23,979)	(19,667)	(24,092)	(5,090)	(4,484)	(5,818)	(5,111)	(21,033)	(25,856)	(34,933)	(7,970)	35,215	88,397
Basic and diluted net loss per share	($10.54)	($4.44)	($2.68)	($0.34)	($0.07)	($0.09)	($0.08)	($0.42)	($0.39)	($0.51)	($0.11)	$0.49	$1.23
Shares of the basic and diluted net loss	2,274	4,427	9,000	15,139	61,056	62,056	62,656	50,227	65,656	68,656	70,656	71,656	71,756
Margin Analysis (% of Sales/Revenue)													
Costs of goods									10%	10%	10%	10%	10%
R&D	83%	165%	941%	335%	424%	1548%	1507%	614%	769%	52%	20%	9%	5%
SG&A	226%	362%	2429%	812%	839%	2794%	2559%	1206%	1553%	108%	41%	16%	9%
Operating Income (loss)	-209%	-427%	-3270%	-1046%	-1163%	-4242%	-3967%	-1720%	-2222%	-190%	-15%	46%	64%
Net Income	-210%	-355%	-3061%	-902%	-891%	-4342%	-3677%	-1591%	-2248%	-191%	-15%	29%	40%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	1332%	-52%	-86%	169%	50%	22%	-3%	68%	-13%	1491%	183%	137%	78%
G&A	-37%	-4%	-19%	-11%	15%	20%	18%	10%	9%	8%	6%	4%	3%
R&D	-48%	-22%	-5%	-6%	-12%	-27%	-21%	-17%	12%	11%	7%	-10%	2%
M&S										7%	5%	7%	5%
Operating Income (Losses)	-62%	-17%	-9%	-8%	-4%	-15%	-10%	-9%	11%	92%	6%	0%	4%
Pretax Income	-62%	-18%	23%	-39%	67%	-16%	-17%	-13%	23%	35%	-77%	-801%	151%
Net Income	-62%	-18%	22%	-39%	67%	-16%	-18%	-13%	23%	35%	-77%	-542%	151%
EPS	-64%	-58%	-40%	-73%	-75%	-87%	-86%	-84%	-6%	29%	-78%	-536%	151%

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

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Additional information available upon request.

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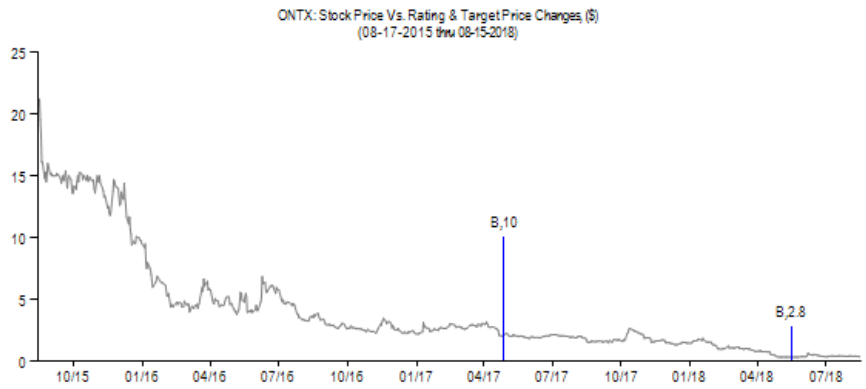
Rating and Price Target Change History



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
05/16/2018	2.80	0.36

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.	61.82%	21.82%	3.64%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.64%	1.82%	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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