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EQUITY RESEARCH
Company Report

May 15, 2017

Onconova Therapeutics (ONTX - $2.10)

Healthcare/Biotechnology

1Q17: Major Focus on the Progression of INSPIRE Study

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

ONTX reported 1Q17 financial results this morning with a net loss of ($8.3MM) vs. Laidlaw ($6.7MM) and the Street ($6.8MM) estimates. The main discrepancy, we believe, is a ~$1.5MM non-cash loss of change in fair value of warrant liability. Net loss/share was ($1.23) vs. ($0.96) for Laidlaw and the Street. ONTX ended 1Q17 with ~$15MM cash and plus the recent financing, we believe ONTX should have sufficient support for operations into late 4Q17.

- **INSPIRE trial updates.** Management pointed out that patient recruitment for the INSPIRE study is underway with 163 sites opened, 60 sites have already enrolled patients. ONTX plans to provide more details on the patient enrollment once all expected clinical sites are activated, for competitive reasons since multiple programs are fighting for patients for clinical studies, given many are in development of 1st- and 2nd- line therapies for MDS. ONTX guided that interim data analysis in 2H17, and completion of patient recruitment in 1H18 is possible. Should this timeline remain on track, topline results could potentially be available several (3-6) months after patient enrollment (possibly in 2H18, in our estimate) based on the historical figure of OS in this patient group. In addition, the FDA is reviewing an INSPIRE trial statistical analysis plan (SAP) for the assumptions and details of the upcoming interim and topline analyses. The agency's response is anticipated in 2Q17. Management also indicated that the INSPIRE trial is expected to enroll MDS patients with more than half categorized as VHR according to the IPSS-R scores. As such, this could potentially bode well for the topline results should the company decide to seek approval either on the ITT or the VHR basis. We also expect the presentation of more data at the ASCO.
- **Oral rigosertib/AZA of 1st-line HR-MDS development updates.** ONTX already submitted a briefing book of the potential Phase III trial design to the EMA for scientific advice. The company plans to submit the protocol to the FDA for a potential SPA designation in 3Q17. As such, we estimate a potential meeting with the FDA to further define the trial protocol could occur in late 2017 or early 2018. Further, ONTX indicated an expansion of the ongoing oral rigosertib/AZA Phase II trial for additional efficacy data and more safety information, including QoL. The objective is to enroll up to 40 new patients in this study
- **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 (5/12/2017)	$2.10
52–Week High (6/9/2016)	$8.17
52–Week Low (4/25/2017)	$2.00
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.

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**	****
		Addition data presentation at the ASCO meeting	**June 2-6, 2017**	***
		Potentially complete Phase III (INSPIRE) patient recuritment	**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

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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	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%

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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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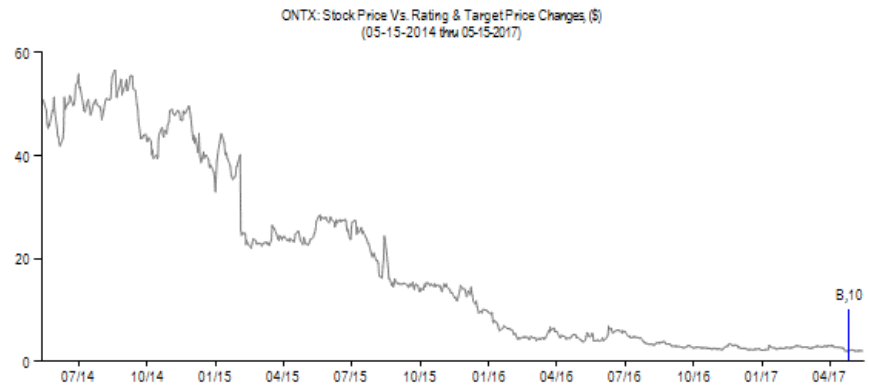
Rating and Price Target Change History



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.	2.27%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	61.36%	29.55%	2.27%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.27%	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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