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EQUITY RESEARCH
Company Report

June 5, 2017

Onconova Therapeutics (ONTX - $1.91)

Healthcare/Biotechnology

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

Management Updates and Oral Rigosertib/Azacitidine in AML Initial Clinical Results at EHA are Encouraging

ONTX presented at the European Hematology Association (EHA) meeting encouraging newly reported oral rigosertib/Aza in acute myeloid leukemia (AML) Phase I/II data and showed the combination exhibiting ORR of 37.5% with median treatment duration of 14.5 months. We also recently met ONTX management and they have indicated that the major developments are on-track with interim data readout for INSPIRE study is scheduled in 2H17 and top-line possibly in 1H18.

- **Details.** At the EHA meeting, ONTX presented a summary of the oral rigosertib/Aza in MDS and AML Phase I/II results. In AML (evaluable n=8), the combination exhibited ORR of 37.5% (n=3) in both secondary and refractory patients (Figure 1). The median treatment duration were 14.5 months. ORR is comprised of morphologic complete remission (25%, n=2), and morphologic leukemia free state (12.5%, n=1). Stable disease (SD) were 25%. The study enrolled 10 AML patients, with 6 relapsed, 2 secondary and 2 transformed from MDS. At separate posters, Phase I study conducted by SymBio indicated that oral rigosertib as a single agent is well-tolerated in Japanese recurrent/relapsed or refractory MDS patients (n=9). ONTX management pointed out during our recent meetings that the company is on-track to potentially conduct the interim analysis of the ongoing INSPIRE study in 2H17, with potential top-line data readout in 1H18. As a reminder, the interim analysis will determine whether the trial will continue as an ITT basis or change to focusing on the IPSS-R based VHR patient cohort. Further, ONTX plans to start a Rasopathies clinical program later with focuses on rare or ultra-rare diseases caused by ras or ras-related mutations. Studies will be funded by NCI and LLS.
- **Implications.** Together, we are encouraged by ONTX's overall development as the interim analysis of their key program (INSPIRE study) remain on-track. Given that the high percentages of patients are more difficult-to-treat elderly (Figure 2) and the regimen appears to be safe, we also view the rigosertib/Aza in AML Phase I/II results promising despite the study size is relatively small and effect was more modest.
- **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 (6/2/2017)	$1.91
52–Week High (6/9/2016)	$8.17
52–Week Low (5/31/2017)	$1.78
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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Figure 1: Oral rigosertib/azacitidine efficacy results in AML

Number of AML patients treated Evaluable for response	10 8
Overall response	3 (37.5%)
Morphologic complete remission Morphologic leukemia free state Treatment failure Stable disease	2 (25%) 1 (12.5%) 3 (37.5%) 2 (25%)
Not evaluable for response (per protocol)	2
Median duration of treatment (months)	14.5

Source: Navada, S.C. et. al., 2017 EHA presentation

Figure 2: Oral rigosertib/aza treatment related characteristics & response

UPN	Age (yrs)	Cohort*	Previous Therapy	DoT (months)	AML Status at Study Entry	IWG Response (D0R) – weeks)
101-033	61	140 bid	1. Induction 2. Investigational	4.0	Refractory	NE
101-002	70	140 bid	Growth Factors	29.6	Secondary	MoCR (25.3)
102-001	76	140 bid	Growth Factors	4.0	MDS/AML	NE
102-003	78	140 bid	Growth Factors	55.1	MDS/AML	MoCR (43)
101-005	73	280 bid	1. Induction 2. DEC x 5	4.0	1st Relapse	TF/I
102-009	71	560/280	1. Induction x 2 2. AZA x 25	12.9	Relapsed	TF/R
102-007	80	560/280	AZA x 5	32.0	Secondary	TF/R
101-008	57	560/280	Induction	8.1	Refractory	MLFS (4.1)
101-009	60	560/280	Induction	24.4	Relapsed	SD
101-007	77	560/280	1. Induction 2. DEC x 5	16.0	Relapsed	SD

MDS/AML – 20 to <30% blasts
NE – patients off study prior to 12 weeks of combination
MoCR – morphologic complete remission
TF/I – treatment failure/indeterminate
TF/R – treatment failure/resistant
MLFS – morphologic leukemia-free state
SD – stable disease

***Oral rigosertib dose**

Source: Navada, S.C. et. al., 2017 EHA presentation

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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**	****
		Potentially complete Phase III (INSPIRE) patient recuritment	**1Q18**	***
		Potentially report Phase III (INSPIRE) top-line results	**1H18**	*****
		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	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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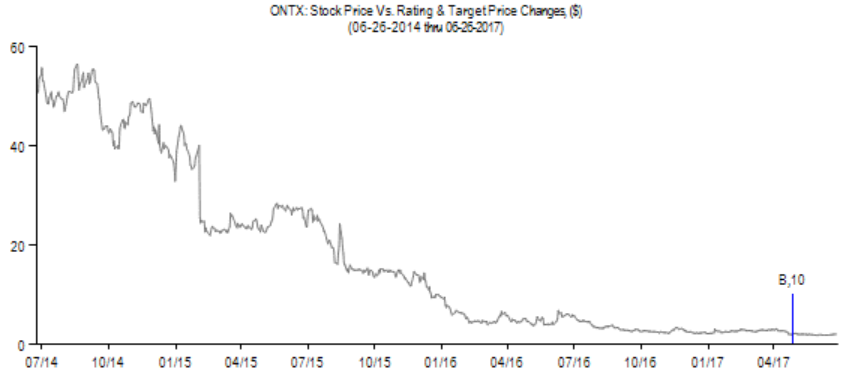
Additional information available upon request.

‡ 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.

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.	64.44%	31.11%	2.22%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.22%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

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