LAIDLAW & COMPANY
Est. 1842
London
New York
San Francisco
Boston

EQUITY RESEARCH
Company Report

October 11, 2017

Onconova Therapeutics (ONTX - $2.36)

Healthcare/Biotechnology

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

RASopathies Day Highlighted Additional Potential for Rigosertib in Treating Rare RAS Centered Disorders

ONTX hosted a RASopathies education day this morning focusing on discussions of two RAS-centered rare pediatric diseases: juvenile myelomonocytic leukemia (JMML) and Noonan syndrome. Highlights include:

- **RASopathies discussions focused on two rare pediatric indications.** Dr. Elliot Stieglitz (UCSF) indicated JMML is an overlapping myelodysplastic/ myeloproliferative disorder caused by hyperactive Ras activities. The disease progresses when a somatic mutation of a second gene (either Ras signaling related or unrelated) occurs. Several Ras-signaling related genes are NF1 (15%), SHP-2 (35%), c-CBL (15%) and Ras-GTP (25%). In addition, epigenetic, mainly genome methylation also plays an important role in the severity of the disease. The prognosis of intermediate or high methylated patients is usually worse. Very preliminary data suggested rigosertib might have some benefit treating JMML. Dr. Bruce Gelb (Mount Sinai, New York) discussed Noonan syndrome, which is with major presentation of developmental delay, hypertrophic cardiomyopathy and short stature. It is one of the rare autosomal dominant disease caused by mutations of several Ras-signaling pathway, such as PTPN11, KRAS, SOS1 and RAF1. Patients with early onset (<6 months) of CHF usually have worse outlook of survival. A Mek inhibitor (PD0325901) has showed some effect in rescuing hypertrophic cardiomyopathy. RAS-related drug like rigosertib could potentially also useful in treating this disorder.
- **INSPIRE trial and oral rigosertib/azacitidine combination expanded study updates.** ONTX reiterated that the interim OS data (88 events or death) from the IV rigosertib in MDS 2nd line pivotal trial (INSPIRE) remain scheduled in 4Q17. The company will also update investors on the status for the full patient enrollment (n=225). In addition, ONTX will provide more updates in 1H18 on the extended clinical study of the oral rigosertib/azacitidine combination as 1st-line MDS treatment. As a reminder, the primary endpoint of the INSPIRE study is OS when 176 events have occurred. After interim analysis, ONTX has the opportunity to explore the potential approval of the very high risk MDS patient with option to amend the trial protocol to recruit more very high risk patients if needed.
- **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 (10/10/2017)	$2.36
52–Week High (4/4/2017)	$3.88
52–Week Low (9/29/2017)	$1.46
Market Cap. (MM)	$24
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

Yale Jen, Ph.D.
Managing Director/Senior
Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

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

Yale Jen, Ph.D.
yjen@laidlawltd.com

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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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%

Yale Jen, Ph.D. 212-953-4978

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

Yale Jen, Ph.D.
yjen@laidlawltd.com

DISCLOSURES:

ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

EQUITY DISCLOSURES

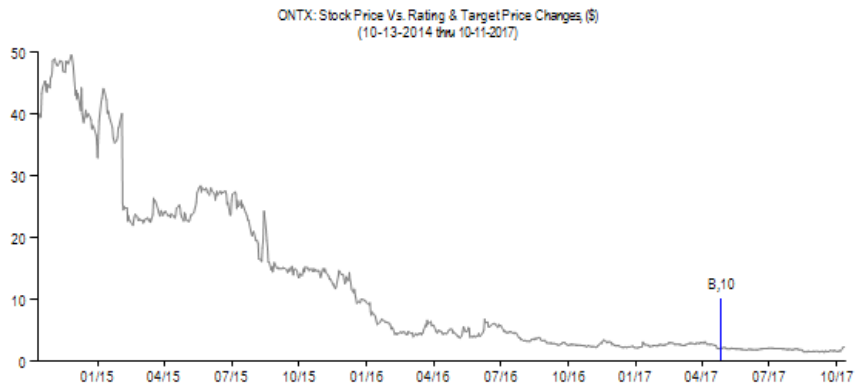
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

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.	64.58%	31.25%	2.08%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.17%	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

ADDITIONAL DISCLOSURES

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

This report does not provide individually tailored investment advice and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. Laidlaw & Co (UK), Ltd. recommends that investors independently evaluate particular investments and strategies, and encourages investors to seek the advice of a financial adviser. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. The securities, instruments, or strategies discussed in this report may not be suitable for all investors, and certain investors may not be eligible to purchase or participate in some or all of them. This report is not an offer to buy or sell or the solicitation of an offer to buy or sell any security/instrument or to participate in any particular trading strategy.

Associated persons of Laidlaw & Co (UK), Ltd not involved in the preparation of this report may have investments in securities/instruments or derivatives of securities/instruments of companies mentioned herein and may trade them in ways different from those discussed in this report. While Laidlaw & Co (UK), Ltd., prohibits analysts from receiving any compensation. Bonus or incentive based on specific recommendations for, or view of, a particular company, investors should be aware that any or all of the foregoing, among other things, may give rise to real or potential conflicts of interest.

With the exception of information regarding Laidlaw & Co (UK), Ltd. this report is based on public information. Laidlaw & Co (UK), Ltd makes every effort to use reliable, comprehensive information, but we make no representation that it is accurate or complete and it should not be relied upon as such. Any opinions expressed are subject to change and Laidlaw & Co (UK), Ltd disclaims any obligation to advise you of changes in opinions or information or any discontinuation of coverage of a subject company. Facts and views presented in this report have not been reviewed by, and may not reflect information known to, professionals in other Laidlaw & Co (UK), Ltd business areas. Laidlaw & Co (UK), Ltd associated persons conduct site visits from time to time but are prohibited from accepting payment or reimbursement by the company of travel expenses for such visits. The value of and income from your investments may vary because of changes in interest rates, foreign exchange rates, default rates, prepayment rates, securities/instruments prices. market indexes, operational or financial conditions of companies or other factors. There may be time limitations on the exercise of options or other rights in securities/instruments transactions. Past performance is not necessarily a guide to future performance. Estimates of future performance are based on assumptions that may not be realized. If provided, and unless otherwise stated, the closing price on the cover page is that of the primary exchange for the subject company's securities/instruments.

The information and opinions in this report were prepared by Laidlaw & Co (UK), Ltd. For important disclosures, please see Laidlaw & Co (UK), Ltd.'s disclosure website at www.Laidlawltd.com, or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

Yale Jen, Ph.D.
yjen@laidlawltd.com

NOTES:

Yale Jen, Ph.D.
yjen@laidlawltd.com