November 13, 2013

OUTPERFORM

Reason for report:

EARNINGS

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LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

ONCONOVA THERAPEUTICS, INC.

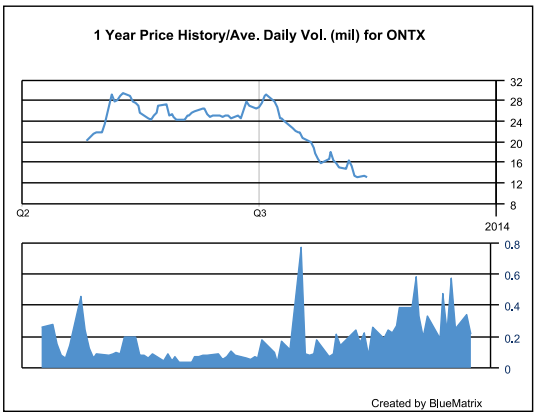
3Q:13 Report -- Pivotal Data Upcoming and Rigosertib Program Expanded

• **Bottom Line:** In conjunction with its 3Q:13 call, ONTX announced the initiation of three new clinical trials: 1) a Phase IIIB study (04-24) of IV rigosertib as a single-agent in high-risk, second-line MDS (myelodysplastic syndrome); 2) a second Phase II trial (09-07) of oral rigosertib in low-risk MDS; and 3) a Phase I/II study (09-08) of oral rigosertib in combination with Vidaza in front-line MDS. Upcoming rigosertib catalysts include top-line data from the Phase III ONTIME trial in high-risk patients in December or 1Q:14, updated data from the Phase II ONTARGET trial in low-risk patients at the American Society of Hematology (ASH – December 7-10), and a pre-planned interim futility and safety analysis of the Phase III ONTRAC trial in pancreatic cancer. Our price target on ONTX remains $37.

• **The 09-07 study in low-risk MDS prohibits the use of erythropoietin-stimulating agents (ESAs).** The recently initiated 09-07 study of rigosertib in low-risk MDS patients is enrolling patients who have previously failed ESA and who will also be denied the use of ESA while on the trial. In the data from the ONTARGET trial presented at the American Society of Clinical Oncology (ASCO) in June 2013, most patients who showed a response to rigosertib had also received an ESA, although the timing and duration of the administration does not appear to correlate with patient response (transfusion independence) (LINK). We await updated data at ASH that are expected to include a subset of patients who were denied ESA use and could provide greater clarity on the prospects for the 09-07 trial. Data on the association of methylation profile and rigosertib-response in the ONTARGET trial are also expected at ASH; however, management would not comment on whether this was being assessed in the new 09-07 trial.

• **The 04-24 trial will examine the relationship between bone marrow blast response and overall survival in high-risk patients.** While previous studies have shown that bone marrow blast level is a clear prognostic factor for overall survival, we are not aware of Phase III results showing a correlation of blast response (seen in the rigosertib Phase I/II trials) and survival. The 04-24 is a single-arm study of 90 high-risk MDS patients who have progressed following treatment with a hypomethylating agent (Vidaza or Dacogen). In addition to assessing bone marrow response, the trial will also allow continued access to rigosertib for high-risk MDS patients and provide additional tolerability and activity data.

Key Stats:	**(NASDAQ:ONTX)**
S&P 600 Health Care Index:	**1,240.86**
Price:	**$13.07**
Price Target:	$37.00
Methodology:	DCF analysis
52 Week High:	$31.13
52 Week Low:	$12.03
Shares Outstanding (mil):	21.4
Market Capitalization (mil):	$279.7
Book Value/Share:	$4.53
Cash Per Share:	$31.28
Dividend (ann):	$0.00
Dividend Yield:	0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	--	--	--	--	$46.2	--	--	--	--	($2.67)	NM
2013E - New	**$1.1A**	**$0.6A**	**$1.1A**	**$1.1**	**$3.9**	**($1.03)A**	**($0.64)A**	**($0.97)A**	**($0.94)**	**($3.54)**	**NM**
2013E - Old	$1.1A	$1.1	$1.1A	$1.1	$4.5	($1.03)A	($0.79)	($0.71)	($0.72)	($3.18)	NM
2014E - New	**--**	**--**	**--**	**--**	**$2.1**	**--**	**--**	**--**	**--**	**($4.35)**	**NM**
2014E - Old	--	--	--	--	$2.1	--	--	--	--	($3.34)	NM

Source: Company Information and Leerink Swann LLC Research
Revenues in millions; EPS are GAAP.

Please refer to pages 6 - 8 for Important Disclosures, Price Charts and Analyst Certification.

INVESTMENT THESIS

ONTX is a late-stage story with robust clinical news flow in the next 6-9 months including pivotal Phase III (ONTIME) data of IV rigosertib in higher-risk second-line myelodysplastic syndrome (MDS). Although the Phase III ONTIME readout is clearly a binary event and there is considerable risk, we believe risk/reward remains favorable. In Phase II trials of higher-risk MDS patients, rigosertib demonstrated good bone marrow (BM) response but more modest hematological improvements. Although we are not aware of data clearly showing a correlation of BM response and survival, we believe the clear correlation of BM blast percentage and survival in historical data is supportive. Another positive consideration is that rigosertib is being compared to best supportive care, and based on our analysis, we do not believe low-dose ara-C will have a meaningful contribution. Although the study is not large for a survival study (270 patients targeted, nearly 300 enrolled), the number of events used for analysis (at least 223) looks reasonable in comparison to the successful AZA-001 study in the first-line setting (195 events). MEDACorp key opinion leaders generally peg the probability of success to be at least 50%, and as high as 80%. We believe rigosertib's opportunity in lower-risk MDS should be viewed independent of the outcome of ONTIME. In contrast to the higher-risk setting, more robust hematological response such as transfusion independence was seen. MEDACorp KOLs view rigosertib data in lower-risk patients to be even stronger than in higher-risk MDS. We believe upcoming ASH data could further solidify the profile. We believe there are limited expectations for pancreatic cancer interim Phase II/III readout in 4Q:13/1Q:14; therefore risk/reward is favorable. We find signals of single-agent activity in head and neck cancer intriguing. ONTX is one of the minority of biotech companies that have been able to maintain full US rights to their lead compound near the finish line. If the Phase III is positive, we believe rigosertib will be an attractive asset to potential acquirers due to retained economics as well as a pipeline of additional indications.

3Q:13 Review and Model Update: Total 3Q:13 revenue was $1.1M, in line with our estimates. Total operating expenses were ($21.2M), higher than our estimates of ($16.4M), driven by both higher R&D and SG&A spend. EPS was ($0.97) versus our estimate of ($0.71). We lowered EPS estimates for 2013 and 2014 to reflect this increased operating expense run rate.

ONTX Expected Events

Event	Time	Comment
Rigosertib		
2nd line, higher risk MDS Phase III topline results (ONTARGET)	Dec '13 - 1Q:14	270+ patients completed enrollment during Dec 2010 - May 2013. Data more likely in 1Q:14.
1st line, lower risk MDS Phase II update (ONTIME)	ASH (Dec 7-10, New Orleans)	Data on ~60 patients expected; data on 34 patients presented at ASCO 2013
1st line pancreatic cancer Phase II/III interim futility / survival analysis (ONTRAC)	Dec '13	Options include: Stop trial, resize trial, or continue as planned

Source: Company reports and Leerink Swann LLC

ONTX Product Pipeline

Agent	Phase	Status/Anticipated Milestones
Rigosertib Single-agent		
2nd-line Higher-risk MDS (IV)	III	Top-line survival results 4Q:13-1Q:14
1st-line Lower-risk MDS (oral)	II	Initital response data 2Q:13; Update at ASH; second Phase II trial (no ESA allowed) initiated in 3Q:13
Head and Neck Cancer (oral)	II	Complete Phase II enrollment 2H:14
Rigosertib in Combination		
1st-line Pancreatic Metastatic (IV) Gemcitabine Comination	III	Interim futility and safety analysis in Dec '13
1st-line MDS (oral) Vidaza Combination	I/II	Intitiated 3Q:13
ON 013105		
Lymphomas and ALL (IV)	I	On-going Phase I Trial
Recilisib		
Acute Radiation Syndromes (SC and oral)	I	Seeking Government Funding

Source: Company reports and Leerink Swann LLC

Valuation

Our 12-month valuation on ONTX shares is $37 based on DCF methodology. We assume rigosertib launches in higher-risk MDS in 2015 and in lower-risk MDS in 2017. Our royalty assumption is 12-19% for ex-US sales. Our projection for peak penetration is 30% for high-risk MDS and 25% for low-risk MDS. Our projection for probability-weighted (60% for higher-risk and 50% for lower-risk MDS) sales of rigosertib reaches $394M for US, and ex-US royalties reach $75M by 2029. We use a discount rate of 10%, which we believe is appropriate given the probability-weighted sales projection.

Risks to Valuation

Risks to our valuation include the following:

Binary clinical risk with Phase III readout of rigosertib in higher-risk MDS. Although Phase II demonstrated bone marrow response, full partial or complete responses by traditional definition were limited, and it is not clear that bone marrow response would predict survival benefit. In addition, although the survival observed in the Phase II compared favorably to historical control, such comparisons are difficult and have significant caveats.

Commercial and execution risks as a small company. The current continuous infusion dosing regimen for the IV formulation may present a challenge.

Financing risk – ONTX has estimated pro forma cash of ~$110M, which we estimate to be sufficient to fund operations through the end of 2014, and the company may have additional financing needs before turning cash flow positive.

ONTX Income Statement ($000)	2011A	2012A	Mar-13A	Jun-13A	Sep-13A	Dec-13E	2013E	2014E	2015E	2016E	2017E	2018E
Collaboration agreements												
Royalties									2,681	6,914	21,868	32,739
Sales									44,678	79,013	168,213	242,512
Total revenue	1,487	46,190	1,116	591	1,116	1,116	3,939	2,116	47,359	85,927	190,080	275,251
COGS										6,874	15,206	19,401
% of revenue										*8%*	*8%*	*8%*
R&D	22,624	52,762	12,756	10,047	15,293	15,446	53,542	69,903	72,000	74,160	76,384	78,676
SG&A	6,436	15,707	3,346	3,117	5,927	5,986	18,376	30,000	67,017	79,013	75,696	84,879
% of revenue									*150%*	*100%*	*45%*	*35%*
Total operating expenses	29,060	68,469	16,102	13,164	21,220	21,432	71,918	96,994	139,017	160,047	167,286	182,956
Net income (loss) from operations	(27,573)	(22,279)	(14,986)	(12,573)	(20,104)	(20,316)	(67,979)	(94,878)	(91,658)	(74,120)	22,794	92,295
Change in fair value of warrant liability	1,287	367	14	(2)	(31)	0	(19)					
Interest expense	(19)	(8,608)	0	(2)	(1)	0	(3)					
Other income, net	11	608	127	15	47	0	189	0	0	0	0	0
Net income (loss) before income taxes	(26,294)	(29,912)	(14,845)	(12,562)	(20,089)	(20,316)	(67,812)	(94,878)	(91,658)	(74,120)	22,794	92,295
Provision (benefit) for income taxes	0	0	0	0	432	0	432	0	0			
Tax rate												
Net income (loss)	(26,294)	(29,912)	(14,845)	(12,562)	(20,521)	(20,316)	(68,244)	(94,878)	(91,658)	(74,120)	22,794	92,295
Accretion of preferred stock	(4,020)	(3,953)	(1,019)	(1,032)	(269)	0	(2,320)	0	0			
Net income (loss) to common stockholders	(30,314)	(33,865)	(15,864)	(13,594)	(20,790)	(20,316)	(70,564)	(94,878)	(91,658)	(74,120)	22,794	92,295
Net loss per share	**(14.18)**	**(2.67)**	**(1.03)**	**(0.64)**	**(0.97)**	**(0.94)**	**(3.54)**	**(4.35)**	**(4.00)**	**(3.08)**	**0.83**	**3.20**
Basic shares	2,137	12,669	15,446	21,389	21,404	21,511	19,937	21,819	22,910	24,055	25,258	26,521
Dilutive shares			15,446	24,186	24,428	24,672	22,183	24,697	24,944	26,191	27,501	28,876

Source: Company Reports and Leerink Swann

LEERINK SWANN

Disclosures Appendix

Analyst Certification

I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

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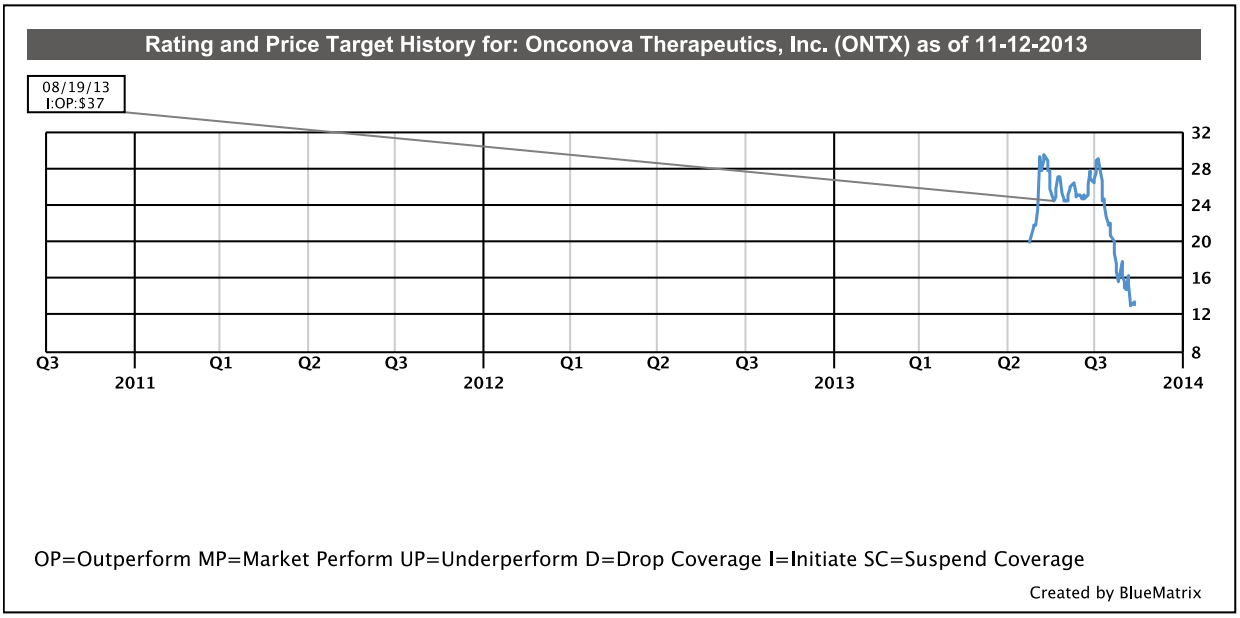

Distribution of Ratings/Investment Banking Services (IB) as of 09/30/13				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	111	64.90	27	24.00
HOLD [MP]	60	35.10	0	0.00
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): **We expect this stock to outperform its benchmark over the next 12 months.**

Market Perform (Hold/Neutral): **We expect this stock to perform in line with its benchmark over the next 12 months.**

Underperform (Sell): **We expect this stock to underperform its benchmark over the next 12 months.The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.**

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

Important Disclosures

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Leerink Swann Consulting LLC, an affiliate of Leerink Swann LLC, is a provider of evidence-based strategy and consulting to the healthcare industry.

In the past 12 months, the Firm has received compensation for providing investment banking services to Onconova Therapeutics, Inc.

Leerink Swann LLC makes a market in Onconova Therapeutics, Inc.

Leerink Swann LLC has acted as the manager for a public offering of Onconova Therapeutics, Inc. in the past 12 months.

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