

Reason for report:

FLASH NOTE

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HEALTHCARE EQUITY RESEARCH

## ONCONOVA THERAPEUTICS, INC.

### Negative Pancreatic Trial Not a Surprise – Hurdle Appears Relatively High

• **Bottom Line:** ONTX announced the discontinuation of the Phase II/III ONTRAC study of IV rigosertib plus gemcitabine (vs. gemcitabine alone) in front-line metastatic pancreatic cancer following a planned interim analysis on the Phase II portion of the data. Given the historical difficulty in pancreatic cancer, we believe Street expectations were low. In addition, incremental color from management indicates the hurdle for the interim analysis was relatively high. Key near-term driver remains Phase III results for IV rigosertib in higher-risk Myelodysplastic Syndrome (MDS) patients, which we expect to be in 1Q:14. In addition, management is hosting an analyst meeting on Thursday (12/19) to discuss opportunities in MDS with key opinion leaders following recent ASH data presentation.

• **Interim analysis represents a look at Phase II portion of the study.** Enrollment in the trial was stopped at 160 patients in May, and this interim analysis was conducted following 125 events, with the data safety monitoring board (DSMB) indicating that the rigosertib arm was unlikely to show a statistically significant improvement in overall survival (OS). There were no safety concerns raised in the DSMB review, which would suggest to us that the survival of the combination arm was not inferior.

• **The hurdle in the interim appears relatively high.** We spoke with management, who indicated that the company gave guidelines to the DSMB that the trial must pass a relatively high efficacy bar to move forward to the full Phase III and the efficacy would need to be at least equivalent to that of Abraxane (which showed hazard ratio of 0.72) so that OS benefit could be demonstrated in a 600-800 patient study. Full data are expected sometime in 2014, most likely at the ASCO annual meeting (5/30-6/3).

#### Key Stats:

(NASDAQ:ONTX)

|                                       |                 |
|---------------------------------------|-----------------|
| <b>S&amp;P 600 Health Care Index:</b> | <b>1,249.43</b> |
| <b>Price:</b>                         | <b>\$16.38</b>  |
| 52 Week High:                         | \$31.13         |
| 52 Week Low:                          | \$11.73         |
| Shares Outstanding (mil):             | 2.6             |
| Market Capitalization (mil):          | \$42.7          |



## 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.

### 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.

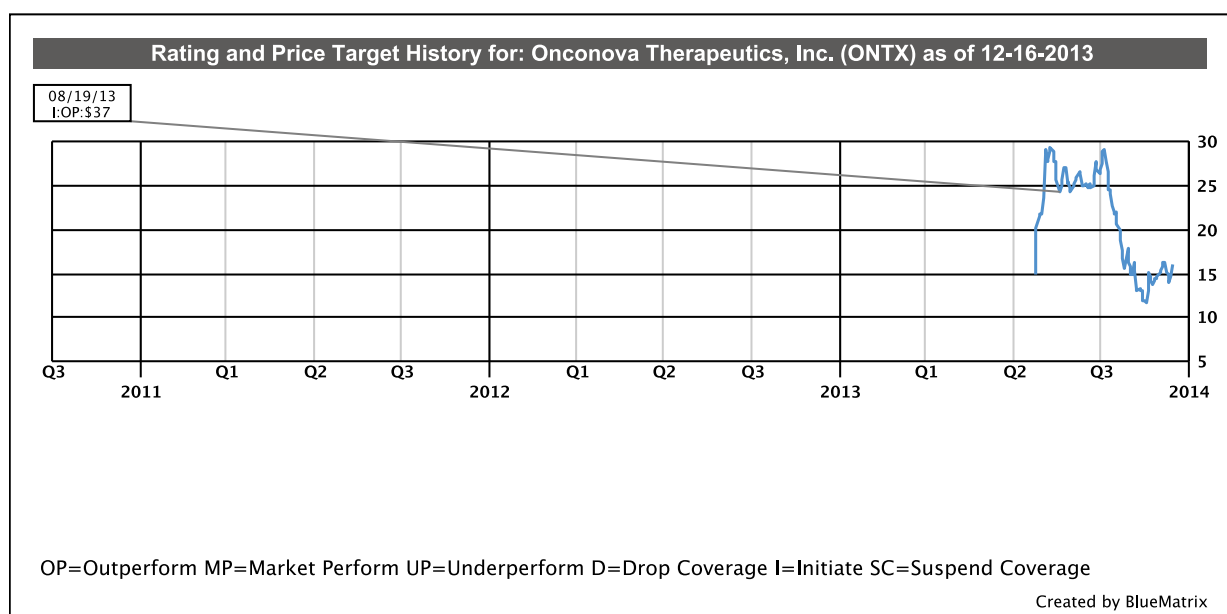
### Risks to Valuation

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.





| Distribution of Ratings/Investment Banking Services (IB) as of 09/30/13 |       |         |                       |         |
|---|-------|---------|-----------------------|---------|
| Rating  | Count | Percent | IB Serv./Past 12 Mos. |         |
|   |       |         | 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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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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