DAWSONJAMES SECURITIES

Member FINRA/SIPC

# INSTITUTIONAL RESEARCH

## *Biotechnology*

## COMPANY UPDATE

Toll Free: 561-391-5555 ♦ www.DawsonJames.com ♦ 1 North Federal Highway - Suite 500 ♦ Boca Raton, FL 33432

*December 20, 2017*

# Onconova Therapeutics (Nasdaq/ONTX)

## BUY INSPIRE progresses, New partnership signed

***Robert M. Wasserman***
**Senior Research Analyst**
**561-208-2905**
**rwasserman@dawsonjames.com**

*Onconova Therapeutics is focused on discovering and developing targeted, small molecule product candidates for the treatment of cancer*

## Investment Highlights

**1) As 2017 comes to an end, Onconova is nearing several milestones relating to its Phase 3 INSPIRE trial for second-line higher-risk MDS patients.** First, the Company is expected to report interim analysis (IA) for the trial late in 2017 or early in 2018 as all 175 sites (across 22 countries) have now been opened and the trigger event (the 88th death event in the 225-patient trial) approaches. Earlier this fall, Onconova received positive guidance from both the US FDA and Europe's EMA regarding the trial's statistical analysis plan (SAP) for both interim and final data analysis, and thus Onconova was able to finalize the plan for the IA. Thanks in part to faster enrollment as more sites were added and new CROs were substituted in certain countries, Onconova now expects full enrollment for INSPIRE by the first half of 2018, with top-line (final) analysis in the second half of next year. Meanwhile, the Company has been active at some high-profile medical conferences, including the recent American Society of Hematology (ASH) annual meeting, including making two presentations on Rigosertib in MDS, one on long-term follow-up of patients in the Phase 2 single-agent trial in lower-risk patients and the other on the mechanism of action of the rigosertib-azacitidine combination therapy.

**2) Onconova is also making progress on its earlier-stage pipeline. Most recently, the Company signed a license and development agreement with China's HanX Bio for ON 123300, a dual inhibitor of CDK 4/6 + ARK5.** Onconova will retain all rights to the versatile oncology compound outside of China, while HanX will fund studies in both the US and China, which will be designed to be IND-compatible. While no financial details were provided regarding the agreement, Onconova's similar deal, with SymBio for Japan/Korea rights for rigosertib for MDS, included a $7.5 million upfront payment and additional considerations still be determined. The whole area of CDK 4/6 compounds is very topical right now, including Pfizer's (PFE, Not Rated) success with Ibrance and new IPO G1 Therapeutics (GTHX,

| | |
|---|---|
| **Current Price** | **$1.51** |
| **Price Target** | **$5.00** |

| Estimates | F2015A | F2016A | F2017E |
|---|---|---|---|
| **Revenues($000s)** | **$11,456** | **$5,546** | **$804** |
| **1Q March** | 114 | 1,474 | 210 A |
| **2Q June** | 123 | 2,248 | 324 A |
| **3Q September** | 1,622 | 1,651 | 110 A |
| **4Q December** | 9,597 | 173 | 160 E |
| | | | |
| **EPS (diluted)** | **($10.54)** | **($4.44)** | **($2.81)** |
| **1Q March** | (3.34) | (2.65) | (1.23) A |
| **2Q June** | (4.13) | (1.96) | (0.29) A |
| **3Q September** | (2.60) | (0.29) | (0.71) A |
| **4Q December** | (0.76) | (0.80) | (0.70) E |
| | | | |
| EBITDA/Share | ($8.80) | ($4.43) | ($2.54) |
| EV/EBITDA (x) | N/A | N/A | N/A |

| Stock Data | |
|---|---|
| 52-Week Range | $1.21-$3.88 |
| Shares Outstanding (mil.) | 9.9 |
| Market Capitalization (mil.) | $14.9 |
| Enterprise Value (mil.) | $7.3 |
| Debt to Capital (9/17) | 0.0% |
| Book Value/Share (9/17) | ($0.62) |
| Price/Book | N/A x |
| Average Trading Volume (3-month) | 207,000 |
| Insider Ownership | 19.6% |
| Institutional Ownership | 25.5% |
| Short interest (Millions) | 0.34 |
| Dividend / Yield | $0.00/0.0% |

Price target and ratings changes over the past 3 yrs:
Initiated - July 25, 2017 - Buy - Price Target $5.00

Not Rated) which has a $500+ million market cap. In other pipeline news, the Company presented studies on its combination rigosertib/azacitidine MDS therapeutic at recent conferences, and Onconova has designed a Phase 3 protocol – which it plans to submit to the FDA early next year to begin the SPA process, which could accelerate additional partnership activity. In addition, Onconova recently hosted a Key Opinion Leader meeting to highlight new approaches to RASopathies, which are related genetic syndromes usually caused by mutations that alter the Ras subfamily, and Onconova has completed and expects to sign a cooperative research and development agreement (CRADA) with the US NIH for rigosertib in pediatric indications.

**3) Onconova recently reported financial results for its Q3/2017 quarter (ending September),** including revenues of $110,000 as compared to $1.65 million one year ago, and a net loss of $7.0 million or ($0.71) per share versus a net loss of $1.6 million or ($0.29) per share for the same period one year ago. Revenues declined this year as a contractual cost-sharing agreement with Baxalta ended last year, while R&D costs rose from $4.0 million last year to $5.1 million in Q3/2017 due to expansion of the INSPIRE Phase 3 trial as well as the Phase 2 combination higher-risk MDS study. General and administrative expenses decreased this year, however, and last year's results included a large positive gain for the change in fair value of warrant liability. Operating activities used approximately $7.4 million of cash in the most recent quarter and $19 million to date this year, up from $3 million and $11.5 million for the same periods last year; at the end of the quarter Onconova had cash and equivalents of about $7.6 million on hand. Notwithstanding any proceeds from new development or licensing agreements, including the recent signing with HanX, the Company most likely will need to raise additional capital in 2018.

**Conclusion/Stock Valuation**

With a Phase 3 trial for second-line high-risk MDS patients well underway and several near-term clinical progress milestones expected in the next 6-12 months, a second Phase 3 trial for first-line HR-MDS patients possibly set to begin as early as sometime next year, a number of other clinical and pre-clinical product candidates waiting for the allocation of additional resources to progress, and a strong balance sheet, ONTX shares may soon attract the attention of growth-oriented investors, especially as clinical and business progress continues to be announced throughout 2017 and into 2018. Still, possibly due to its smaller size and lower investor profile, these shares continue to trade at a valuation discount to industry peers in the oncology and hematology therapeutic markets, and value investors may also soon be attracted to ONTX shares. Thus, we believe ONTX shares may soon follow those of other oncology-oriented biotechnology companies which have recently exhibited strong price appreciation, and therefore we are maintaining our Buy rating on ONTX shares and 12-18 month price target of $5.00 per share. (For additional explanation of our Stock Valuation for ONTX please refer to our Initiation Report dated July 25, 2017).

**Catalysts**

Clinical program development and other milestones to look for from Onconova for the rest of this calendar year and into next year include:

1) Release of Phase 3 clinical trial interim analysis for IV rigosertib in MDS – early 2018;
2) Release of top-line data for Phase 3 clinical trial for IV rigosertib in MDS - 2018;
3) Initiation of Phase 3 trial for combination oral rigosertib/azacitidine - 2018 (with additional funding); and
4) Business development activity for preclinical and early-stage product candidates, including potential development partnerships, marketing agreements, government grants/collaborations, and/or new product in-licenses – 2018-2019.

**Risk Factors**

**In addition to normal economic and market risk factors that impact most equities and the common risks shared by Onconova Therapeutics with other companies in the industry, we believe an investment in ONTX involves the following risks:**

- **Reliance on key management** – At present, ONTX relies on several key members of its management team who either founded the Company or have been in key executive positions for an extended period of time. Should one or more of these key executives leave the Company, ONTX could find it difficult to replace their long-standing knowledge of operations and industry expertise.
- **Reliance on partnerships –** To date, ONTX has signed development partnerships and joint ventures for its clinical-stage therapeutics. Thus, in the future certain factors related to product marketing and/or new product development may be determined by third parties and out of the control of Company management.
- **Limited stock liquidity** – Trading volume in ONTX stock is comparatively light and these shares have a relatively limited history of trading compared with other healthcare stocks. As such, news regarding ONTX, its target market, partners and/or competitors could lead to significant volatility in the stock price.
- **Competitive markets** – The Company and its partners compete in its target therapeutic markets with a number of companies, many of which are considerably larger than the Company. There can be no assurance that the Company and its partners will be able to successfully compete and launch new products into these competitive markets in the future.
- **FDA and regulatory risks** – ONTX and its partners are subject to regulatory review for ongoing therapeutic products research and development, principally approval and review processes of the US Food and Drug Administration and other non-domestic regulatory agencies. In addition, the quality assurance and manufacture of the Company's therapeutic products are subject to ongoing oversight and regulation, and any negative correspondence from the FDA or other regulatory agencies could have an adverse effect on the ongoing operations of the Company.
- **Lack of historic profitability** - ONTX has not achieved operating profitability since its founding, and according to our forecasts may not be expected to do so in the near future. Although the Company maintains adequate cash reserves at the present time, there can be no assurance the Company will not need to raise additional working capital in the future should operating losses continue.
- **Need to defend patents and other intellectual property** – ONTX currently holds approximately 79 US and International patents on its rigosertib product candidate, as well as additional patents and patent applications for its earlier-stage and preclinical drug candidates, some of which expire in the near future. The Company may be required to defend its patents in the US and overseas in the future, and there can be no assurance these defenses will be successful.

Robert M. Wasserman

**Onconova Therapeutics, Inc.**
**Consolidated Statements of Income**
**(In 000s, except per share data)**

| FYE December | 2014 | 2015 | 1Q16 March | 2Q16 June | 3Q16 September | 4Q16 December | 2016 | 1Q17 March | 2Q17 June | 3Q17 September | 4Q17E December | 2017E | 2018E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Revenue | $800 | $11,456 | $1,474 | $2,248 | $1,651 | $173 | $5,546 | $210 | $324 | $110 | $160 | $804 | $6,500 |
| Operating Expenses | | | | | | | | | | | | | |
| General and administrative | 15,119 | 9,533 | 3,172 | 2,083 | 1,975 | 1,948 | 9,178 | 2,116 | 1,779 | 1,728 | 1,800 | 7,423 | 10,000 |
| Research and development | 49,425 | 25,895 | 5,822 | 5,564 | 3,991 | 4,694 | 20,071 | 4,886 | 4,614 | 5,141 | 5,200 | 19,841 | 21,000 |
| Total operating expenses | 64,544 | 35,428 | 8,994 | 7,647 | 5,966 | 6,642 | 29,249 | 7,002 | 6,393 | 6,869 | 7,000 | 27,264 | 31,000 |
| Income (loss) from operations | ($63,744) | ($23,972) | ($7,520) | ($5,399) | ($4,315) | ($6,469) | ($23,703) | ($6,792) | ($6,069) | ($6,759) | ($6,840) | ($26,460) | ($24,500) |
| Other income (loss) | 81 | 9 | 280 | 18 | 2,716 | 1,036 | 4,050 | (1,549) | 3,484 | (202) | (200) | 1,533 | (500) |
| Net income (loss) before taxes | ($63,663) | ($23,963) | ($7,240) | ($5,381) | ($1,599) | ($5,433) | ($19,653) | ($8,341) | ($2,585) | ($6,961) | ($7,040) | ($24,927) | ($25,000) |
| Income taxes | 19 | 16 | | | | | 14 | | | | | 100 | 100 |
| Net income (loss) | ($63,682) | ($23,979) | | | | | ($19,667) | | | | | ($25,027) | ($25,100) |
| Basic income per share | ($29.41) | ($10.54) | ($2.65) | ($1.96) | ($0.29) | ($0.80) | ($4.44) | ($1.23) | ($0.29) | ($0.71) | ($0.70) | ($2.81) | ($1.67) |
| Diluted income per share | ($29.41) | ($10.54) | ($2.65) | ($1.96) | ($0.29) | ($0.80) | ($4.44) | ($1.23) | ($0.29) | ($0.71) | ($0.70) | ($2.81) | ($1.67) |
| Basic shares outstanding | 2,165 | 2,274 | 2,732 | 2,740 | 5,438 | 6,797 | 4,427 | 6,771 | 8,999 | 9,851 | 10,000 | 8,905 | 15,000 |
| Diluted shares outstanding | 2,165 | 2,274 | 2,732 | 2,740 | 5,438 | 6,797 | 4,427 | 6,771 | 8,999 | 9,851 | 10,000 | 8,905 | 15,000 |
| Key ratios: | | | | | | | | | | | | | |
| Revenue growth | N/A | 1332.0% | 1193.0% | 1727.6% | 1.8% | -98.2% | -51.6% | -85.8% | -85.6% | -93.3% | -7.5% | -85.5% | 2995.2% |
| G &A/revenue | 1889.9% | 83.2% | 215.2% | 92.7% | 119.6% | 1126.0% | 165.5% | 1007.6% | 549.1% | 1570.9% | 1125.0% | 923.3% | 153.8% |
| R&D/revenue | 6178.1% | 226.0% | 395.0% | 247.5% | 241.7% | 2713.3% | 361.9% | 2326.7% | 1424.1% | 4673.6% | 3250.0% | 2467.8% | 323.1% |
| Tax Rate | 0.0% | -0.1% | 0.0% | 0.0% | 0.0% | 0.0% | -0.1% | 0.0% | 0.0% | 0.0% | 0.0% | -0.4% | -0.4% |
| Deprec, amort & non-cash comp. | 3,958 | 3,958 | 1,920 | 630 | (2,100) | (410) | 40 | 2,030 | (1,000) | 600 | 650 | 2,280 | 10,000 |
| Cash Flow/share | ($27.58) | ($8.80) | ($1.95) | ($1.73) | ($0.68) | ($0.86) | ($4.43) | ($0.93) | ($0.40) | ($0.65) | ($0.64) | ($2.55) | ($1.01) |
| EBITDA/share | ($27.57) | ($8.80) | ($1.95) | ($1.73) | ($0.68) | ($0.86) | ($4.43) | ($0.93) | ($0.40) | ($0.65) | ($0.64) | ($2.54) | ($1.00) |

**Balance Sheets**
($000s)

| *Assets:* | 12/31/16 | 9/30/17 |
|---|---|---|
| Current Assets | | |
| Cash and equivalents | $21,400 | $7,600 |
| Receivables | 31 | 57 |
| Prepaid expenses and other current assets | 1,638 | 1,050 |
| Total current | 23,069 | 8,707 |
| Property and equipment, net | 152 | 83 |
| Other long-term assets | 12 | 12 |
| Total Assets | $23,233 | $8,802 |
| *Liabilities:* | | |
| Current liabilities | | |
| Accounts payable | $5,323 | $5,436 |
| Accrued expenses and other current | 4,382 | 3,098 |
| Deferred revenue | 455 | 455 |
| Total current | 10,160 | 8,989 |
| Warrant liability | 3,401 | 1,686 |
| Deferred revenue and other non-current | 4,545 | 4,205 |
| Total liabilities | 18,106 | 14,880 |
| Stockholders' equity | 5,127 | -6,078 |
| TOTAL LIAB & EQ | $23,233 | $8,802 |

**Quarterly Earnings Comparisons**

| | March | June | September | December | Total |
|---|---|---|---|---|---|
| **Revenues (in $Mill)** | | | | | |
| 2014 | | | | | 800 |
| 2015 | 114 | 123 | 1,622 | 9,597 | 11,456 |
| 2016 | 1,474 | 2,248 | 1,651 | 173 | 5,546 |
| 2017E | 210 | 324 | 110 | 160 | 804 |
| **Earnings per Share (diluted)** | | | | | |
| 2014 | | | | | (29.41) |
| 2015 | (3.34) | (4.13) | (2.60) | (0.76) | (10.54) |
| 2016 | (2.65) | ($1.96) | (0.29) | ($0.80) | (4.44) |
| 2017E | (1.23) | ($0.29) | (0.71) | ($0.70) | (2.81) |

**Revenues by Segment**

| (In $000s) | 2015 | 2016 | 2017E | 2018E |
|---|---|---|---|---|
| LLS (The Leukemia and Lymphoma Society) | 8,000 | | | |
| Baxalta | 2,893 | 4,999 | | |
| SymBio | 563 | 547 | 800 | 1,500 |
| Other/New | 0 | 0 | 0 | 5,000 |
| Total | $ 11,456 | $ 5,546 | $ 800 | $ 6,500 |

*Source: Dawson James Securities, Inc. estimates; Company documents*

**Important Disclosures:**

**Price Chart:**


Price target and ratings changes over the past 3 years:
Initiated – Buy - July 25, 2017 – Price Target $5.00

Dawson James Securities, Inc. (the "Firm") is a member of the Financial Industry Regulatory Authority ("FINRA") and the Securities Investor Protection Corporation ("SIPC").

The Firm does not make a market in the securities of the subject company (s). The Firm has NOT engaged in investment banking relationships with ONTX in the prior twelve months, as a manager or co-manager of a public offering and has NOT received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has received other compensation from the subject company(s) in the last 12 months for services unrelated to the managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. As of November 30, 2017, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company (s) of this report. The Firm, its officers, directors, analysts or employees may effect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the company(s) subject to this report. The Firm may effect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

**Information about valuation methods and risks can be found in the "STOCK VALUATION" and "RISK FACTORS" sections of this report.**

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only, and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

**Ratings Definitions:**

1) **Buy**: the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
2) **Neutral**: the analyst believes the price of the stock is fairly valued for the next 12-18 months;
3) **Sell**: the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

| | Company Coverage | | Investment Banking | |
|---|---|---|---|---|
| **Ratings Distribution** | # of Companies | % of Total | # of Companies | % of Totals |
| Market Outperform (Buy) | 14 | 88% | 3 | 21% |
| Market Perform (Neutral) | 2 | 0% | 0 | 0% |
| Market Underperform (Sell) | 0 | 0% | 0 | 0% |
| Total | 16 | 100% | 3 | 19% |

**Analyst Certification:**

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.