November 12, 2013

# Onconova Therapeutics, Inc. Reports Third Quarter 2013 Financial and Operational Results

NEWTOWN, Pa., Nov. 12, 2013 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (Nasdaq:ONTX) a clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, today provided a corporate update and reported financial results for the third quarter ended September 30, 2013.

"Onconova made important progress during the third quarter, significantly expanding the clinical development program for our most advanced product candidate, rigosertib, with the initiation of three new clinical trials," commented Ramesh Kumar, Ph.D., President and CEO of Onconova. "Rigosertib has been evaluated in more than 1,000 patients in clinical trials thus far and its dual PI3K/PLK pathway inhibition provides broad therapeutic potential. We anticipate key upcoming milestones in the development of rigosertib, including the presentation of results from the Phase 2 trial in lower risk myelodysplastic syndromes (MDS), top-line results from the Phase 3 trial in higher risk MDS, and results from an interim analysis of the Phase 3 trial in pancreatic cancer."

**Recent Milestones in the Rigosertib Clinical Development Program**

- Initiated enrollment in three new clinical trials that expand the development of rigosertib in lower risk and front-line MDS patients:
  -- The 04-24 study: A 90-patient, single-arm Phase 3B study that continues exploration of intravenous (IV) rigosertib as a single agent therapy for higher risk MDS patients who have progressed on or after treatment with azacitidine or decitabine. This trial will examine the relationship between bone marrow blast response and overall survival and provide continued access to rigosertib to patients for this unmet medical need. This study will provide additional tolerability and activity data helpful for future commercialization activities.
  -- The 09-07 study: A second Phase 2 study with single agent oral rigosertib in lower risk MDS patients after they have failed erythropoiesis-stimulating agents (ESAs). This 40-patient, multi-center trial complements the ONTARGET study and further explores the safety and the possible effects of rigosertib in transfusion-dependent, lower risk MDS patients who have failed ESA treatment.
  -- The 09-08 study: A Phase 1/2 study testing the combination of oral rigosertib and azacitidine (Vidaza®, a hypomethylating agent indicated for first-line treatment of MDS patients) in up to 40 patients with MDS. This trial will determine the maximum tolerated dose of rigosertib that can be given with azacitidine and assess the safety, tolerability, and activity of this novel combination therapy.

**Key Upcoming Milestones**

**MDS**

- Data presentations at the American Society of Hematology (ASH) Annual Meeting, including results from the Phase 2 ONTARGET trial. This trial evaluates efficacy, tolerability, and dosing regimen of oral rigosertib in transfusion-dependent, lower risk MDS.
- Top-line survival results from the Phase 3 ONTIME trial of IV rigosertib in higher risk MDS patients who failed treatment with hypomethylating agents are now anticipated in either December, 2013 or the first quarter of 2014. This trial reached its enrollment target of 270 patients in the second quarter of 2013. Positive results from this trial would enable filing of a New Drug Application (NDA) in the second half of 2014, and a Marketing Authorization Application (MAA) in the fourth quarter of 2014 or the first quarter of 2015.

**Pancreatic Cancer**

- A pre-planned interim futility and safety analysis in the Phase 3 ONTRAC trial of IV rigosertib plus gemcitabine in front-line metastatic pancreatic cancer is expected in December, 2013.

**Third Quarter and Nine Months 2013 Financial Results**

- Cash, cash equivalents, and marketable securities as of September 30, 2013 totaled $116.6 million compared to $81.5 million at December 31, 2012.
- Total net revenue was $1.1 million for the third quarter of 2013 and $2.8 million for the nine months ended September 30, 2013, compared to $42.8 million and $43.2 million for the comparable periods in 2012. In the third quarter of 2012, the Company entered into a licensing and development agreement with a subsidiary of Baxter International Inc. ("Baxter"). Baxter made an upfront payment of $50 million of which $42.6 million was recognized as revenue in the third

quarter of 2012.

- Research and development expenses were $15.3 million for the third quarter of 2013 and $38.1 million for the nine months ended September 30, 2013, compared to $27 million and $42.2 million for the comparable periods in 2012. In the third quarter of 2012, the Company made a $12.5 million milestone payment in accordance with its license agreement with Temple University. Additionally, in both comparable periods in 2013, there was a decrease in stock-based compensation expense, resulting primarily from a change in accounting method during 2013, which was partially offset by an increase in clinical trial expenses and headcount.
- General and administrative expenses were $5.9 million for the third quarter of 2013 and $12.4 million for the nine months ended September 30, 2013, compared to $8.9 million and $13 million for the comparable periods in 2012. There was a decrease in stock-based compensation expense in 2013 compared to 2012, resulting primarily from a change in accounting method during 2013. The decrease was partially offset by an increase in headcount.
- Net loss was $20.5 million for the third quarter of 2013 and $47.9 million for the nine months ended September 30, 2013, compared to $1.4 million and $19.7 million for the comparable periods in 2012.

**Conference Call Information**

Onconova will host a conference call today at 4:30 pm ET to discuss the quarter and provide a corporate update. To participate in the conference call, please dial (877) 312-5881 (domestic) or (253) 237-1173(international) five minutes prior to the start of the call and provide the passcode 97336840.

The recorded, listen-only webcast of the conference call can be accessed under "Events & Presentations" in the Investor and Media section of the Company's website at www.onconova.com. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company's website for two weeks following the call.

**About Onconova Therapeutics, Inc.**

Onconova Therapeutics is a clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer. Onconova's clinical and pre-clinical stage drug development candidates are derived from its extensive chemical library and are designed to work against specific cellular pathways that are important in cancer cells, while causing minimal damage to normal cells. In addition to rigosertib, the Company's most advanced product candidate, two other candidates are in clinical trials, and several candidates are in pre-clinical stages. For more information, please visit http://www.onconova.com.

**Forward Looking Statements**

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements relate to future events or Onconova Therapeutics, Inc.'s future operations, clinical development of Onconova's product candidates and presentation of data with respect thereto, expectations regarding the sufficiency of Onconova's cash balance to fund operating expenses and capital expenditures, milestone or royalty payments from Onconova's collaborators, Onconova's anticipated milestones and future expectations and plans and prospects. Although Onconova believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under the heading "Risk Factors" in our Registration Statement on Form S-1 originally filed with the Securities and Exchange Commission on June 14, 2013, as amended (Registration No. 333-189358).

Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

**Onconova Therapeutics, Inc.**

**Condensed Consolidated Balance Sheet**

*(in thousands)*

| | September 30, 2013 | December 31, 2012 |
|---|---|---|
| | (unaudited) | |
| **Assets** | | |
| Current assets: | | |

| | | |
|---|---|---|
| Cash and cash equivalents | $ 76,612 | $ 81,527 |
| Marketable securities | 39,990 | -- |
| Prepaid expenses and other current assets | 5,326 | 1,725 |
| Total current assets | 121,928 | 83,252 |
| Property and equipment, net | 652 | 463 |
| Other non-current assets | 137 | 137 |
| Total assets | $ 122,717 | $ 83,852 |
| **Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,405 | $ 5,517 |
| Accrued expenses and other current liabilities | 7,898 | 3,987 |
| Option liability | -- | 11,967 |
| Deferred revenue | 2,530 | 3,907 |
| Total current liabilities | 14,833 | 25,378 |
| Deferred revenue, non-current | 14,023 | 15,421 |
| Other | 30 | 44 |
| Total liabilities | 28,886 | 40,843 |
| Redeemable convertible preferred stock | -- | 201,315 |
| Stockholders' equity (deficit): | | |
| Preferred stock | -- | -- |
| Common stock | 214 | 26 |
| Additional paid in capital | 309,916 | 10,021 |
| Accumulated other comprehensive loss | (18) | -- |
| Accumulated deficit | (216,281) | (168,353) |
| Total stockholders' equity (deficit) | 93,831 | (158,306) |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit) | $ 122,717 | $ 83,852 |

**Onconova Therapeutics, Inc.**

**Condensed Consolidated Statements of Operations (unaudited)**

*(in thousands, except share and per share amounts)*

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| Revenue | $ 1,116 | $ 42,803 | $ 2,823 | $ 43,221 |
| Operating expenses: | | | | |
| General and administrative | 5,927 | 8,922 | 12,390 | 13,009 |
| Research and development | 15,293 | 26,962 | 38,096 | 42,186 |
| Total operating expenses | 21,220 | 35,884 | 50,486 | 55,195 |
| Income (loss) from operations | (20,104) | 6,919 | (47,663) | (11,974) |
| Change in fair value of warrant liability | (31) | (25) | (19) | 365 |
| Interest expense | (1) | (8,357) | (3) | (8,608) |
| Other income, net | 47 | 28 | 189 | 567 |
| Net loss before income taxes | (20,089) | (1,435) | (47,496) | (19,650) |
| Income taxes | 432 | -- | 432 | -- |

| | | | | |
|---|---|---|---|---|
| Net loss | (20,521) | (1,435) | (47,928) | (19,650) |
| Accretion of redeemable convertible preferred stock | (269) | (785) | (2,320) | (2,943) |
| Net loss applicable to common stockholders | $ (20,790) | $ (2,220) | $ (50,248) | $ (22,593) |
| | | | | |
| Net loss per share of common stock, basic and diluted | $ (1.34) | $ (1.02) | $ (7.23) | $ (10.36) |
| Basic and diluted weighted average shares outstanding | 15,480,416 | 2,174,392 | 6,946,248 | 2,181,795 |

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