# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

### **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 8, 2012

# ONCOGENEX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other Jurisdiction of Incorporation)

033-80623 (Commission File Number)

95-4343413 (IRS Employer Identification No.)

1522 217th Place S.E. Bothell, Washington (Address of Principal Executive Offices)

98021 (Zip Code)

Registrant's telephone number, including area code: (425) 487-9500

(Former name or former address if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions: Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition.

On November 8, 2012, OncoGenex Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the third quarter of 2012. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press release of OncoGenex Pharmaceuticals, Inc. November 8, 2012

The information in Item 2.02 of this Form 8-K and Exhibit 99.1 attached hereto is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ONCOGENEX PHARMACEUTICALS, INC.

Date: November 8, 2012

/s/ Michelle Burris Michelle Burris Chief Financial Officer

	EXHIBIT INDEX
Exhibit No.	Description

99.1 Press release of OncoGenex Pharmaceuticals, Inc. dated November 8, 2012

#### OncoGenex Pharmaceuticals, Inc. Provides Clinical Development Update and Reports Financial Results for Third Quarter 2012

Conference call to be held on Thursday, November 8, 2012 at 4:30 p.m. Eastern Time

**BOTHELL, WA., and VANCOUVER, British Columbia, November 8, 2012** – OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) today announced third quarter 2012 financial results and highlighted key clinical development activities of its two product candidates, custirsen and OGX-427.

#### **Custirsen Clinical Development Highlights**

- The Company announced completion of patient enrollment in the primary registration Phase 3 SYNERGY study. The SYNERGY study is designed to evaluate a survival benefit for custirsen, when added to first-line chemotherapy, in men with metastatic castrate-resistant prostate cancer (mCRPC). Over 1000 men have now been enrolled. The survival primary endpoint data are event-driven and results are expected by the end of 2013.
- The Phase 3 AFFINITY study, evaluating a survival benefit for custirsen in combination with Jevtanæ (cabazitaxel) as second-line chemotherapy in approximately 630 men with CRPC, was initiated in the third quarter. This global study will be conducted at sites throughout North America, Europe and Australia
- The ENSPIRIT trial, an international, randomized Phase 3 study in approximately 1,100 patients with advanced or metastatic non-small cell lung cancer (NSCLC), was initiated in the third quarter. The trial will evaluate the potential survival benefit of combining custirsen with docetaxel as a second-line chemotherapy in patients who have progressed after initial chemotherapy treatment has failed.

#### **OGX-427** Clinical Development Highlights

• Preliminary data from an investigator-sponsored Phase 2 clinical trial of OGX-427 in chemotherapy-naïve patients with metastatic CRPC were presented at the European Society for Medical Oncology Annual Meeting (ESMO) in September 2012. The updated study results showed a higher number of patients without disease progression at 12 weeks and greater declines in prostate-specific antigen (PSA) and circulating tumor cells (CTC) with OGX-427 plus prednisone treatment compared to prednisone alone. The study continues to demonstrate an acceptable safety profile of OGX-427 and final study results are expected in 2013.

- The randomized, Phase 2 clinical trial of OGX-427 in patients with metastatic bladder cancer continues patient accrual, with sites throughout North America and Europe. The trial aims to enroll approximately 180 patients and will evaluate the overall survival benefit of OGX-427 in combination with gemcitabine and cisplatin.
- An investigator-sponsored, randomized Phase 2 study evaluating OGX-427 in combination with Zytiga (abiraterone acetate) in patients with CRPC is expected to begin enrollment in late 2012 or early 2013.

#### Third Quarter 2012 Financial Update and Results

- Revenue for the third quarter and nine months ended September 30, 2012 increased to \$6.6 million and \$10.3 million, respectively, compared with \$1.2 million and \$4.3 million, respectively, in the same periods in 2011. The increase in 2012 as compared to 2011 was due to higher revenue earned through our strategic collaboration with Teva, resulting from clinical development activities associated with the AFFINITY trial.
- As of September 30, 2012, \$9.1 million of the \$30 million advanced reimbursement received from Teva in December 2009 was included on our Balance Sheet as Current Deferred Collaboration Revenue. This advance reimbursement balance will continue to be reduced as we incur direct and indirect custirsen development costs. As a consequence of initiating the AFFINITY trial, we continue to expect that all remaining Current Deferred Collaboration Revenue will be recognized as Collaboration Revenue by the fourth quarter of 2012. Once the remaining amount of the advanced reimbursement from Teva has been drawn to zero, all of our costs associated with the clinical programs under our collaboration will be reimbursed by Teva quarterly.
- Total operating expenses for the third quarter and nine months ended September 30, 2012 increased to \$14.9 million and \$30.1 million, respectively, compared with \$5.3 million and \$18.6 million, respectively, in the same periods in 2011. The increase in 2012 as compared to 2011 was due primarily to higher clinical study expenses associated with the startup of the AFFINITY trial, patient enrollment in our clinical trial evaluating OGX-427 in patients with metastatic bladder cancer and associated manufacturing costs and higher employee expenses, including stock based compensation expenses. These increases were partially offset by lower preclinical expenses.

- Net loss for the third quarter and nine months ended September 30, 2012 was \$5.9 million, or \$0.40 per diluted common share, and \$17.0 million, or \$1.29 per diluted common share, respectively. This is compared with net income of \$4.5 million, or \$0.45 per diluted common share in the three months ended September 30, 2011 and a net loss of \$5.1 million, or \$0.52 per diluted common share for the nine months ended September 30, 2011. The net loss in the three and nine months ended September 30, 2012 included a non-cash gain on revaluation of our warrant liability of \$2.3 million and \$2.5 million, respectively. The net income in the three months ended September 30, 2011 included an \$8.6 million non-cash gain on revaluation of our warrant liability and the net loss in the nine months ended September 30, 2011 included a \$9.0 million non-cash gain on revaluation of our warrant liability.
- We had \$85.1 million in cash, cash equivalents and short-term investments as of September 30, 2012, compared to \$64.9 million as of December 31, 2011.
- 2012 cash guidance:
  - o Annual net cash requirements are expected to be in the range of \$45 million to \$50 million.
  - o Year-end cash, cash equivalents, investments and receivables from Teva are expected to be in the range of \$68 million to \$73 million and include the receipt of proceeds from our March offering of common stock.
- Based on our current expectations, we believe our capital resources as of September 30, 2012 will be sufficient to fund our currently planned operations into 2015.
- At November 7, 2012, we had 14,656,916 shares outstanding.

## Consolidated Statements of Loss (Income) (In thousands, except per share and share data) (unaudited)

	Three months	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011	
Collaboration revenue	\$ 6,570	\$ 1,174	\$ 10,315	\$ 4,260	
Operating expenses:					
Research and development	12,895	3,814	24,303	14,076	
General and administrative	1,965	1,457	5,749	4,499	
Total operating expenses	14,860	5,271	30,052	18,575	
Loss from operations	8,290	4,097	19,737	14,315	
Other income (expense)	2,370	8,567	2,742	9,211	
Loss (income) for the period before income taxes	5,920	(4,470)	16,995	5,104	
Income taxes					
Net loss (income)	\$ 5,920	\$ (4,470)	\$ 16,995	\$ 5,104	
Basic net loss (income) per share	\$ 0.40	\$ (0.46)	\$ 1.29	\$ 0.52	
Diluted net loss (income) per share	\$ 0.40	\$ (0.45)	\$ 1.29	\$ 0.52	
Weighted average number of basic common shares	14,619,842	9,736,589	13,141,940	9,722,836	
Weighted average number of diluted common shares	14,619,842	10,043,821	13,141,940	9,722,836	

# Consolidated Balance Sheets (In thousands)

	September 30, 2012 (unaudited)	December 31, 2011
Assets:		
Cash, cash equivalents, short term investments and restricted cash	\$ 85,387	\$ 65,304
Amounts receivable	1,138	812
Prepaid and other current assets	9,292	1,210
Property, equipment and other assets	1,355	689
Total assets	\$ 97,172	\$ 68,015
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	\$ 5,718	\$ 3,217
Deferred collaboration revenue	9,145	18,271
Current portion of long-tem obligations	1,451	1,417
Warrant liability	5,359	7,881
Long term liabilities	5,738	6,339
Stockholders' equity	69,761	30,890
Total liabilities and stockholders' equity		\$ 68,015

#### **Conference Call Details**

OncoGenex will host a conference call at 4:30 p.m. Eastern Time today, Thursday, November 8, 2012, to provide a business update and discuss the third quarter results. A live event will be available on the Investor Relations section of the OncoGenex Web site at <a href="https://www.OncoGenex.com">www.OncoGenex.com</a>. Alternatively, you may access the live conference call by dialing 877-606-1416 (U.S. & Canada) or 707-287-9313 (International). A replay of the webcast will be available approximately two hours after the call and will be archived for 90 days.

#### ABOUT ONCOGENEX

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new therapies that address treatment resistance in cancer patients. OncoGenex has a diverse oncology pipeline, with each product candidate having a distinct mechanism of action and representing a unique opportunity for cancer drug development. OncoGenex and Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) have entered a global collaboration and license agreement to develop and commercialize OncoGenex' lead drug candidate, custirsen. Custirsen is currently in Phase 3 clinical development as a treatment in men with metastatic castrate-resistant prostate cancer (CRPC) and in patients with advanced, unresectable non-small cell lung cancer. OGX-427 is in Phase 2 clinical development in CRPC and metastatic bladder cancer. OGX-225 is currently in pre-clinical development. More information is available at www.OncoGenex.com.

#### **OncoGenex' Forward Looking Statements**

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning our anticipated product development activities, such as expected clinical trial completion, statements regarding the potential benefits and potential development of our product candidates and statements regarding our expected financial results and our expected future cash resources and liquidity. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements. Such forward-looking statements are subject to risks and uncertainties, including, among others, the risk that final trial results will not demonstrate the same or any potential benefit as observed in preliminary trial results, the risk that subsequent studies may not confirm earlier trial results, the risk of delays in our expected clinical trials, the risk that new developments in the rapidly evolving cancer therapy landscape require changes in our clinical trial plans or limit the potential benefits of our product, the risk that our cash requirements are greater than expected or that our resources are insufficient to fund our planned activities for the time period expected and the other factors described in our risk factors set forth in our filings with the Securities and Exchange Commission from time to time, including the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. The Company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

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SOURCE: OncoGenex Pharmaceuticals, Inc.