## 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): June 7, 2010

# **ONCOGENEX PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware	033-80623	95-4343413
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
1522 217th Place S.E. Bothell, Washington		98021
(Address of Principal Executive Of	fices)	(Zip Code)
	ephone number, including area code: (4: <u>N/A</u> me or former address if changed since la	·
Check the appropriate box below if the Form 8-I	ç	. /
any of the following provisions:		
□ Written communications pursuant to Rule 42:	5 under the Securities Act (17 CFR 230.4	425)
□ Soliciting material pursuant to Rule 14a-12 un	nder the Exchange Act (17 CFR 240.14a	-12)
□ Pre-commencement communications pursuan	t to Rule 14d-2(b) under the Exchange A	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 7.01 Regulation FD Disclosure.

On June 7, 2010, OncoGenex Pharmaceuticals, Inc. issued a press release entitled "OncoGenex Pharmaceuticals Announces Final Results from Phase 1 Trial Evaluating OGX-427 as a Treatment for Solid Tumors". A copy of the press release is attached as Exhibit 99.1 and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this report, including the exhibit attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall such information 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 a filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1

Press release of OncoGenex Pharmaceuticals, Inc. dated June 7, 2010

#### 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: June 7, 2010

/s/ Cameron Lawrence

Cameron Lawrence Principal Financial Officer

## EXHIBIT INDEX

Exhibit No.Description99.1Press release of OncoGenex Pharmaceuticals, Inc. dated June 7, 2010



# OncoGenex Pharmaceuticals Announces Final Results from Phase 1 Trial Evaluating OGX-427 as a Treatment for Solid Tumors

Results Presented at ASCO 2010 Annual Meeting Confirm Acceptable Safety Profile and Evidence of Biological Activity Including Declines in Circulating Tumor Cells and Reductions in Tumor Markers

**BOTHELL, WA, and VANCOUVER, June 7, 2010** — OncoGenex Pharmaceuticals, Inc. (NASDAQ: OGXI) today announced final results from a Phase 1 trial. The primary purpose of this trial was to evaluate the safety and tolerability of OGX-427 up to doses of 1000 mg for the treatment of various solid tumors. Patients enrolled had a diagnosis of castrate resistant prostate cancer, breast cancer, ovarian cancer or non-small cell lung cancer. Final results showed that OGX-427 was safe and well tolerated as a monotherapy as well as in combination with docetaxel. In addition, OGX-427 when used as a single agent demonstrated declines in circulating tumor cells at all doses and in all diseases evaluated, as well as evidence of reduction in tumor markers in prostate and ovarian cancer. Results were presented today at the 46<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO).

"These final Phase 1 data confirm the interim safety and biological activity profile of OGX-427 initially presented during an oral presentation at the ASCO 2009 Annual Meeting," said Cindy Jacobs, Executive Vice President and Chief Medical Officer of OncoGenex Pharmaceuticals. "We are encouraged by the anti-tumor activity seen in this trial and we're looking forward to additional evaluation of OGX-427 as a single agent and in combination with chemotherapy in the treatment of cancer."

OGX-427 is designed to reduce levels of Hsp27, a heat shock protein that is over-produced in response to many cancer treatments including hormone ablation therapy, chemotherapy, and radiation therapy. In preclinical models, Hsp27 production has been shown to inhibit cell death in tumor cells through a variety of mechanisms.

The Phase 1 trial evaluated 36 patients treated with OGX-427 as a single agent and 12 with OGX-427 in combination with docetaxel who had failed up to six prior chemotherapy regimens. OGX-427 as a single agent administered weekly was evaluated at doses from 200 mg up to 1000 mg in five cohorts of approximately six patients in each cohort. Two further cohorts tested OGX-427 at the 800 and 1000 mg doses combined with docetaxel. Patients could receive up to ten 21-day cycles.

#### Safety Results

When OGX-427 was given as a single agent, a median of two cycles (range: 0-8 cycles) was administered. Most adverse events were mild (grade 1 or 2) and mainly occurred during the three "loading doses" given over nine days prior to weekly dosing. The majority of adverse events felt to be related to OGX-427 consisted of grade 1 or 2 fever, chills, itching, or flushing (associated with the infusion of OGX-427) and fatigue. Infusion reactions were mainly seen at the 800 and 1000 mg doses and required very few infusion interruptions, delays, or modifications. The most common laboratory grade 3 or 4 adverse events were a low lymphocyte count or a prolonged PTT (a coagulation test) which were not associated with increased infections or bleeding.

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When OGX-427 was combined with docetaxel, a median of six cycles (range: 1-10) was administered. Infusion reactions continued to be the most common adverse events, followed by nausea, back pain, poor appetite and shortness of breath. As expected in patients receiving docetaxel chemotherapy, the most common grade 3 or 4 laboratory event was a low neutrophil count with febrile neutropenia (fever without infection with a low neutrophil count) occurring in only two patients.

Only one patient at the 600 mg dose when OGX-427 was given as monotherapy demonstrated a dose-limiting toxicity, with no other dose-limiting toxicity observed at higher doses or when OGX-427 was administered in combination with docetaxel chemotherapy. Despite evaluating OGX-427 at very high doses, a maximum tolerated dose for OGX-427 was not reached in this study.

#### **Observations of Therapeutic Activity**

When OGX-427 was used as monotherapy, three of 17 evaluable patients had a decrease in measurable disease of 20% or greater. In this heavily pretreated patient population, two of four patients with ovarian cancer had a decrease of 25% or greater in CA-125 (an ovarian tumor marker) and three of 15 patients with prostate cancer had a decrease of 30% or greater in PSA (a prostate tumor marker).

Of particular interest was the decrease in both total circulating tumor cells (CTCs) and CTCs which were positive for Hsp27 (Hsp27<sup>+</sup> CTCs). Recent studies have shown that the presence of CTCs in peripheral blood may be of prognostic significance for solid tumors, and patients with values of five cells or less are generally considered to have a favorable prognosis. In nine of 26 evaluable patients, the total CTCs had decreased to five tumor cells or less, while Hsp27<sup>+</sup> CTCs decreases were noted in all diseases evaluated and in 89% of patients treated. In addition, serum Hsp27 protein levels were decreased by 30% or greater over a period of at least six weeks in approximately 25% of patients at the 800 and 1000 mg doses.

When OGX-427 was combined with docetaxel, five of 10 patients had a decrease in measurable disease of 20% or greater. Five of nine patients with prostate cancer had a decrease of 30% or greater in PSA. Again, decreases in both total CTCs and Hsp27<sup>+</sup> CTCs were observed. Hsp27<sup>+</sup> CTCs were decreased in 71% of patients treated. In five of seven evaluable patients, the total CTCs had decreased to 5 cells or less. Serum Hsp27 protein levels were decreased by 30% or greater over a time period of at least six weeks in approximately 35% of patients.

"OGX-427 was safe and well tolerated at the doses evaluated, and evidence of biological activity was observed even at the 400 mg dose of OGX-427 given as a single agent," said Dr. Kim Chi, Principal Investigator and a medical oncologist at the British Columbia Cancer Agency, Vancouver, British Columbia. "The declines in PSA and circulating tumor cells indicate potential for therapeutic activity and warrant continued investigation into randomized Phase 2 trials which we anticipate initiating this year."

#### About OGX-427

OGX-427 is designed to reduce levels of Hsp27, a protein that is over-produced in response to many cancer treatments including hormone ablation therapy, chemotherapy and radiation therapy. Hsp27 production has been shown to inhibit cell death in tumor cells through a variety of mechanisms.

The OGX-427 Phase 1 clinical data presented at ASCO evaluates OGX-427 for the systemic (intravenous) treatment of solid tumors including prostate, non-small cell lung, breast, and ovarian cancers. OncoGenex announced preliminary results of this Phase 1 trial presented during an oral presentation at the 2009 American Society of Clinical Oncology (ASCO) Annual Meeting.



In August 2009, OncoGenex announced the first patient dosed in an open label, dose-escalation, Phase 1 clinical trial evaluating OGX-427 when administered directly into the bladder (intravesical instillation) in patients with bladder cancer. The study is sponsored by the National Cancer Institute of Canada (NCIC).

OncoGenex expects that a randomized, controlled, investigator-sponsored Phase 2 clinical trial evaluating OGX-427 when administered as a monotherapy to patients with castrate resistant prostate cancer will initiate in mid-2010.

#### About OncoGenex

OncoGenex is a biopharmaceutical company committed to the development and commercialization of new cancer therapies that address treatment resistance in cancer patients. OncoGenex has a deep 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 (NASDAQ: TEVA) have entered a global collaboration and license agreement to develop and commercialize OncoGenex's lead drug candidate, OGX-011. The companies project to initiate two Phase 3 trials in castrate resistant prostate cancer in Q2 and Q3 2010, and a third Phase 3 trial in non-small cell lung cancer in early 2011; OGX-427 is in Phase 1 clinical development; SN2310 has completed a Phase 1 clinical trial; and CSP-9222 and OGX-225 are currently in pre-clinical development. More information about OncoGenex is available at www.oncogenex.com.

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 statements concerning the clinical benefit of OGX-427, anticipated clinical development activities, timing of these activities, and the ability of future trials to demonstrate clinical benefit. 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.

The potential risks and uncertainties associated with forward-looking statements include, among others, the possibility that any clinical benefit will not be maintained or will become less substantial as patient survival follow up continues, risks that clinical trials will not be successful or confirm earlier clinical trial results, including the risk that the clinical benefit will not be confirmed in additional clinical trials, risks associated with obtaining funding from third parties or completing a financing necessary to support the costs and expenses of additional clinical trials, the timing and costs of clinical trials and regulatory approvals will be different than management currently anticipates, risks relating to the development, safety and efficacy of therapeutic drugs and potential applications for these products and the risk factors set forth in the Company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K for fiscal year 2009. The Company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof.

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